PESTICIDE PROGRAM DIALOGUE COMMITTEE MEETING

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P R O C E E D I N G S

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MR. SHARP: Let me say good morning, and thanks for being here this morning. I know it is a full agenda, as you all scanned through it and have seen it. We have a lot of items on the plate for the next day and a half, a lot of very important issues, a lot of things that I know a lot of folks around this table have been involved in for a number of years or certainly have expertise in and advice for the Agency, and we look forward to hearing all your discussion and working through a number of briefings that we've also prepared and updates that we've also prepared to give to you all.

I just wanted to note something. I don't know how many of you have been around for the full life of PPDC, but I wanted to at least -- Pineapple raised her hand. Maybe there's a few others around here, too. There certainly are some who have been on PPDC for pretty much its entire extent. But

congratulations to you all. This is, interestingly, the ninth year of PPDC, and a lot of you have been involved in this committee, this advisory group, for much of that time, if not all of that time, but there's also many of you who haven't been, who are relatively new to the group or have just come to the group in the last several years, and we welcome you and want to say that this group is very important to the Agency.

We have had a lot of experiences, a lot of issues, a lot of dialogue, et cetera, with this advisory group that's been invaluable to us. When you look back at what we've done, what we've accomplished, what we've been able to get advice from this group on in order to move forward on, we have a very good I think history of accomplishments that we've been able to accomplish because of your input and dedication to this group.

FQPA, let me just mention, we're a year and ten months away from the FQPA deadline. So,

the clock is ticking. We're over 7000 tolerances now re-assessed. With the advice that you've given to us, many of you through this group and also through the carat and track groups, we've been able to create a more open, transparent process, one that involves stakeholders, much more than we've been able to in the past. So, real changes there.

You have also been able to help us lay the foundation for the implementation of PRIA. We've talked a lot about endangered species, and there's going to be a session tomorrow on the Endangered Species Protection Program. So, a new issue or a newer issue, I should say, that we're now looking for continued advice on.

And then, of course, most importantly, the reduction in risk of pesticides that we've been able to accomplish. In doing so, still providing the tools that are needed for agriculture, registering newer, safer products, and being able to continue to operate as a program and be efficient and be effective as a

program. So, those are all things that I give credit to a lot of the people around this table, because of your advice, your dedication to the various issues, whether or not they're the large, big picture issues that are potential show-stoppers or things that the program needs to figure out, like an FQPA implementation, all the way down to small issues that are day to day, regulatory or policy decisions that many people just don't focus on.

You've been invaluable on both the big and the small, many opportunities that we've had to bring these issues up to you all and ask for specific individuals around the table many times to take time out of your schedules, to take time between meetings to do work, to provide advice to us that is ultimately very helpful, and we thank you all for that.

Now you are giving us advice on a new phase, on a new transition into the 15-year rolling review, and we look forward to that session. We're going to have some discussion on

that here in just a few minutes. So, that's another phase that you are going to be helping us with. So, we look forward to that.

I want to thank you on behalf of Administrator Levitt, on behalf of Steve Johnson, on behalf of Susie Hazen, and myself and all of our EPA colleagues for taking the time to be here again today and tomorrow and thanking you for all your hard work and dedication to this group. Also to the other agencies that are here, USDA, FDA, Interior and others have been a part of these groups, Fish & Wildlife representative as well, I think we have here, I mentioned Interior as well, but Fish & Wildlife is going to be here shortly.

So, we continue to grow and try to bring in other agencies as needed and as pertinent and as specifically in some of these newer issue areas, like endangered species, wanting to try in those agencies and making sure that the Federal Government is hearing from all of our stakeholders as we're moving down these

paths. So, those are all very important to us.

So, once again, thank you, and let me go ahead and turn the microphone over to Jim.

MR. JONES: Thanks, Adam, I really appreciate your attendance and your comments as well.

I want to thank all of you as well on behalf of the Pesticides Program for your attendance here today and tomorrow. I know how hard it is for all of you to be able to devote the kind of time and attention that you do to making these meetings. You all have busy jobs and busy lives, and I appreciate the commitment that you've made to the PPDC.

You've heard some of this before, but I think it's important to mention again, that the Pesticide Program Dialogue Committee is a Federal Advisory -- operates under the Federal Advisory Committee Act, which is a law that governs how the United States Government can get advice, and so there are rules that surround that, and they involve basically making sure

that there is representation amongst your advisers, all of you, that we are broad -- we are seeking broad stakeholder participation, and that it is in an open and transparent manner. So, we put our agendas on the Federal Register, we announce these meetings in the Federal Register, and these meetings are open to the general public.

And I think it's important for us to remember that, one, this is -- you're an advisory committee. You're here to give the Government, in this case the Office of Pesticide Programs, advice, and there are rules around how we operate, largely involving equity in participation and fairness and openness in the way in which we operate.

One of the things I've learned over the nine years of the PPDC is just how hard it is for us to get advice, and it's hard because the issues that we deal with, the issues that we need advice on, tend to be pretty complicated, and one of the things that we've tried to do

over the last couple of years is to ask you to increase your engagement in this -- in the PPDC to more than just the two or three meetings that we have a year. I have found it hard, and I think that many of you have observed to us, that it's very difficult in an hour and a half, maybe two hours over the course of a day and a half or two days, to really give meaningful advice on some of the complicated issues that we're facing in the Pesticides Program.

So, we have tried in the Pesticides Program to increase our commitment, our level of engagement, between the meetings, and we have asked you to increase your commitment, your level of engagement, between the meetings on these issues so that we can devote meaningful time on some of the very complex issues that we face between meetings so that we can come to these meetings and you can benefit from that knowledge, that in-depth look at an issue, and provide more meaningful advice, and I think that we are off in that respect to a good start.

I think that that's captured in both the registration review work as well as the pesticide education -- safety education program. That, though, is going to be something that I have a commitment to, and I'm really looking for you to maintain that commitment for those of you who have been able to engage with us on some of these issues in between meetings, and for those of you who haven't, to really think about, can you really meaningfully give this Agency advice unless you're giving some of your time, energy and effort in between meetings on some of these complicated issues?

And I think that this morning's discussion around registration review, for those of you who haven't participated in that particular exercise -- which is fine -- I think you will see that we are going to benefit from the depth of engagement that many of you had, and some of you who we brought into it to make sure that we had enough depth and breadth in the stakeholder participation, that it really does

enhance the nature and the type of advice that the Agency can get, and that's really what this is all about, is getting advice and that it's informed advice.

Which does remind me, actually, Margie noted that we are in the -- you all know Margie, I know -- we're in the Jefferson Room here at the Marriott, and inside, if you all will open your folders, there is a quote that Margie told me has been a quote that the Agency has had as part of its ethic for 30 years, since we started, and Margie, when she came to the Pesticides Program, she's made sure it's this quote that's in our folders and has been since the PPDC started.

The quote is -- it's from Thomas Jefferson -- it says, "People are inherently capable of making proper judgments when they are properly informed," and I think that that captures what it is that we're trying to do in this forum and in many of the fora that we engage in in EPA when we're talking about

stakeholder participation. It's about getting advice that's properly informed, and it's really important to be properly informed when you're going to proffer your advice, frankly to anyone, but as far as I'm concerned, it's most important when you're doing it to my organization.

So, it's really important for all of you to think about your investment, not just at these meetings, but between these meetings, and I know, looking around the room, that many of you have given us many hours between the last meeting and this meeting on some of the issues that we're going to be talking about today, and I want to thank you all.

We'll briefly go over the agenda, talk not just about what they are, because you can see what they are, but a little bit of insight into what it is we're trying to achieve.

The first session, as you see, is registration review, I think pretty straightforward there. We have had a work group that's been working quite -- for a little bit

over a year and I think is prepared to give us their insights into registration review, which is, if you haven't followed this very closely, registration review is the statutorily mandated successor to reregistration. It will be the old chemicals program that EPA has when reregistration and tolerance reassessment are over, and we are going to have a brief summary from our team about the work that's been going on over the past months, and then some of the work group members -- this is a work group, PPDC work group -- work group members are going to give their perspective on a number of issues that they have identified through that process.

As we do at each PPDC, there are a couple of topics that we give some program updates. These are areas where either you've told us you'd like to hear what's going on or they're areas we think it's important to communicate what is going on. They tend to be little, you know, 10-15 minute updates, and we have four of those scheduled for a little bit

later this morning.

This afternoon, after lunch, we talked at our last meeting about PRIA process improvements, and the recommendation that we got from the PPDC was that you were comfortable with a -- setting up a work group that focused on process improvements and that that work group, which has been working over the last six months, come back to the PPDC with status reports so that we could get from you your sense as to whether or not these process improvements were worth the Agency going forward with, investing with. We are going to hear from that group early this afternoon.

That will be then followed by a discussion around -- first about the OPP budget. We'll talk a little bit about our '04 budget and what it is and the status of the '05 budget, which is still very much in play. We'll give you that perspective with a focus on the office's discretionary extramural resources, and the reason that we're doing that, if you'll

recall, has to do with the discussion we had the last time around, the Pesticide Safety Education Program, where as we talked about that, it became very clear to me that getting advice on how much we spend on any one program was not particularly properly informed, as Thomas Jefferson would say, unless you understood all of the other -- the trade-offs and the choices, and I think it was actually Caroline and Steve Ball who both said they weren't prepared to give advice around that unless they understood what the trade-offs were. So, Marty is going to -- Marty Monell is going to walk us through the broader budget issues, basically the extramural resources available to us that are discretionary, so that that -- people can look at that in the context of PSEP to give us some sense as to what your advice would be around PSEP and PSEP funding going forward.

We're then going to talk about what we also committed to doing at the last PPDC, which was a program review of the Pesticide Safety

Education Program, and Bill Diamond from the Field and External Affairs Division is going to talk about what we've done in that, and we're going to hear from some other stakeholders who have been participating in that exercise as well.

We'll end the day, before public comment, which we always do, with a few more updates, updates that I think of in terms of accountability, what our basic programs, registration, reregistration, are doing. We are also going to give you a heads-up on some work around fumigants that I think will be of keen interest to many of you around the table.

Tomorrow morning, our representative from the tribal perspective is going to give us a presentation in the morning at 9:00. That will be followed by -- I think we'll be -- will hopefully be a very informative, interesting, and I think that we will be able to get some solid advice on an issue associated with endangered species, in particular, what we'll be

looking for -- we're going to describe how we think, as we implement the Endangered Species Program at EPA, where in that process there is time for public participation and how we think we can engage the public, and that is the kind of issue I think you can basically give a 30-minute -- 20-minute presentation, say here are the points where we think we can get public participation, and that is enough information for many of you to be able to say, you know what, I think I like that or I don't like that, I'd like to get more or less or -- of course, if there is -- people want to think about it, share it with some of the people you represent, that's perfectly fine as well, but we'll be letting you know, taking a first stab of how we think we can get public participation in our Endangered Species Protection Program implementation and begin to get some feedback from all of you.

Again, we will end with public comment, and that should make for a pretty solid day and a half. I'm very hopeful that it will be a

meaningful day and a half, not just of information exchange, but that the Agency will get some very meaningful advice during the next day and a half.

Before I turn over the mic to Jay and Susan, first I'd just like to say that -- since I chair this meeting, I get to say that we're all honorary members of the Red Sox Nations today. Sorry, Yankee fans. I would also like to acknowledge, we will -- Dr. Greg Mason from the Fish & Wildlife Service will be here with us later today, and Burleson and Al from USDA, and Burleson Smith, who's going to give a few welcoming remarks as well. Thanks.

MR. SMITH: So, we're talking baseball today? No.

No, on behalf of the Department, I would just like to thank my colleagues at EPA for including us in this opportunity. I think oftentimes we're all very happy to provide advice to the Agency, and quite frankly, this is an opportunity for us to listen to those of you

from the PPDC committee. Thank you very much for your participation in this. We benefit greatly from listening to your interchange at these meetings. So, again, thank you on behalf of the Department of Agriculture for your input, your time and service on this committee, and again, Jim, Adam, thank you very much for the opportunity to join you up here and to listen, so...

MR. SHARP: Thanks.

MR. JONES: Okay, Jay and Susan, let's get started on our first agenda item this morning.

MR. ELLENBERGER: Thank you, Jim. I'm Jay Ellenberger, with the Office of Pesticide Programs, and my colleague, Susan Lewis, is to my right. She and I have made presentations at the last few PPDC meetings to share with you the progress that the Agency is making on the registration review rule and in collaboration with our work group that's composed of both public and private sector representatives, and

it's -- the work group has been very cooperative and collaborative in providing Susan and me with advice and working through some very significant issues. As Jim said or Adam said at the start, that a lot of the issues that we deal with and bring here are complex, and the registration -- building a new old chemicals program, the registration review program, is -- has a lot of complexities in it, and we've benefitted immensely from getting input, advice, good creative ideas from this work group. So, we really appreciate that.

This morning, after I give a brief review for those of you who might be new or just, you know, memory refresher, where we've come on developing the registration review program, Susan will give a summary of a very important, pivotal project that we did at the suggestion of the PPDC last spring, to do a feasibility study on how well we think the project or the program that we've designed to date would work, and she'll go over, give you

some I think very interesting results of that feasibility study.

Then, Erik Olson, representing NRDC, will give his perspectives and those also of George Wichterman, from the Lee County Mosquito Control District, perspectives on public participation for this new program, followed by Julie Spagnoli from Bayer HealthCare talking about data needs for this program and how data needs for chemicals going through the registration review program sort of would fit in and different kinds of options and approaches to that.

Then I will follow it up with a couple new issues and open it up for full discussion. So, with that, a few slides to bring us up to the feasibility study that Susan's going to talk about.

We started the registration review process with an advance notice of proposed rulemaking four years ago, and the last couple years, we've been very aggressively working with

the PPDC work group on a number of key issues. As I've already mentioned, conducting a feasibility study in the spring and summer and also working on drafting the proposed rule, which right now is within the Agency for review and concurrence.

We're on schedule for publishing our proposed rule this winter, beginning of next calendar year, and taking public comments, making any appropriate revisions, and then plan on a final rule being published in hopefully spring of 2006, so that by August or so of 2006, we will have the program in full swing. So, those are our goals, and we are committed to them and very optimistic that we will be able to achieve those. Next.

In thinking about the registration review program, being the -- sort of the new version of reregistration or the old chemicals program, knowing that the -- what Congress has laid out for us in Section 3(g) of FIFRA, we have got to figure out a way of doing our

assessments much more efficient, much quicker. We're looking for high efficiency, 50 chemicals cases or about 80 active ingredients a year. That's substantially more than what the current reregistration program output is. We need to continue with the goals of sound science, transparency, have a very open process, and of course, our decisions need to be credible.

We also recognize that to be able to accomplish this, that the process has to be quite flexible, that it's not a one-size-fits-all, be flexible with regard to how we put chemicals of different complexities with different kinds of issues, use patterns and so forth, through the process.

As I mentioned in my opening remarks, that the -- you all and the work group that we work with have been very beneficial to providing recommendations to us in thinking about how we build and construct and design the registration review program, and the recommendations that we've heard from PPDC are the program needs

reliable, predictable schedule, what chemicals are we going to do next year, the following year, so on and so forth, so that not only registrants but other stakeholders can participate in a meaningful timely way. We need to find a way to address new issues for chemicals as they -- as those issues arise, outside of the registration review project or process, if necessary.

We need to tailor the review program to the depth and scope of the issues. New data may be required. We've got to be, again, flexible, figuring out how to take chemicals of different kinds of complexity, with different kinds of science or regulatory issues through the process so they don't get bogged down.

And then lastly, the registration review process should be a safety net. It's a way of dealing with labeling issues, some data issues, new risk assessment issues, so on and so forth, to bring a chemical up to date with current data requirements, regulatory and

science policies and so on and so forth.

The tailored approach that I've been talking about and that we've designed so far with the help of the work group is the idea of assembling a baseline of information for each chemical case and the active ingredients in that case. Basically, what do we know about the chemicals in that case when we begin a registration review? What do we know about the current registrations, the studies that the Agency has on file that we've reviewed to date? What do the last risk assessments tell us about the chemical and its risk characterizations? The use patterns? What kind of incident reports might we have on file? Build a public document that the public can see that kind of information, have access to and think about how it may or may not want to play in that particular registration review for that chemical.

That's an opportunity for not only the Agency but stakeholders to ask the question,

basically, what's changed since the last time EPA did a risk assessment on the active ingredients in that? Has the science changed? Have policies changed? Have the regulations or the statute changed? Incidents, databases changed? So on and so forth.

So, it's, again, an opportunity to ask those very important questions of what the Agency needs to do to do the new risk assessments or the new evaluation for registration review.

The last slide that I'm going to share with you before turning the mic over to Susan to talk about the feasibility studies is just this flow chart that many of you have seen before at the last PPDC meeting. It's a very simplistic diagram of the process that we've designed to date, starting with the top center, of identifying and assembling the database that I just mentioned and getting stakeholder input, providing an opportunity for industry, public interest groups, other regulatory agencies to

provide any additional information into that document.

Before the Agency starts sort of its robust review of that information, to ask the question, are any new assessments required for the active ingredients in this case? So, it's sort of a yes or no question there on our part.

If the answer is no, we think everything is up to date, then we proceed to issuing a decision document for that chemical case. If we do, on the other hand, do think that we do need to do some new risk assessments, again, either new data has come in, incident reports are significantly new, science policy has changed, so on and so forth, then we've got to ask the question, do we have all the data we need to do those new risk assessments, and then proceed accordingly to either get the data, or we don't need any, conduct new risk assessments, to lead us to, again, the decision for completing registration review for that chemical case.

So, it's a very simplistic way of looking at it. Again, we need to -- as I said, our goal is to build flexibility within this system, have some chemicals -- and you'll hear Susan talk about some examples that we think would go through this flow process rather quickly and others that are going to be -- have a lot more complexity to them that's going to take some time.

So, with that, let me turn this over to Susan, who's going to tell you about I think a very exciting, very beneficial study that we did on the feasibility.

MS. LEWIS: Good morning. First I'd like to acknowledge the group that really did the effort within Pesticide Programs on this feasibility study. The last time we had been talking, we had had an extremely valuable advice from the PPDC, and we decided to move on to a feasibility study. We had to carry out this study in a relatively short time frame, very concentrated effort, and Jay and I were very

fortunate to get the group of individuals we did within the Pesticide Programs. They're not all here, but I just would like to acknowledge, and if you can raise your hand, because after our presentation and during the coffee break, you may like to talk to a few of these individuals as well.

T. J. Wyatt was really instrumental in the design and the sampling of the program. Ray Kent chaired the HED, human health side of the assessment. Debbie Schmiegel in Antimicrobials did both the risk management/risk assessor side. Dana Spatz in Environmental Effects and Linda Hollace -- I'm not sure if Linda's here -- within BPPD. And then within the group where I am within Special Review and Reregistration, Stephanie Plummer-Kendra and Morris Johnson really did an amazing effort. So, I just wanted to acknowledge that it was really a group effort.

Over the time we've been talking about principles of reg review and you saw the flow

chart, so they're really kind of abstract thoughts in design, and we thought we would take it more closer to the ground and get something concrete to see if this process could work. So, the purpose of what we did was really to test our decision process and also, twofold, to gather data. We needed data on costs for the economic analysis that has to go in hand for our proposed rule.

So, what we did with T. J.'s help was we randomly through a computer-generated model selected 28 cases that were potential candidates for the first five years of registration review. So, if you remember, we were going to kind of go on a schedule of oldest first. So, generally the oldest ones would be those chemicals that were registered at the end of 1984, early '85, and then you pick up those first new compounds that had had a reregistration in the early nineties, so that the case that we pulled from really was from late '84 to about end of 1995, early 1996.

So, we picked 28 cases out of a total possible 283, roughly 10 percent, and Jay had talked to you about the baseline information. So, what we did internally was gather what do we know in-house? We only stuck to what we had within the Pesticides Program.

The pilot was conducted in a short time frame, very concentrated, as I said, really from June to the end of July or through August, and it was a mixture of both risk assessors and risk managers working on this. Next slide, please.

To give you a sense of the sample size, we were looking at conventional chemicals, antimicrobial chemicals and biologicals. You have displayed sort of what the sample size was and what the population. Overall, we went with a 10 percent. We tended to select slightly higher on the biological side. Our initial thought were those may not be -- we wanted to have a larger sample to ensure we had some compounds that would require added data needs so we could assess those. Next.

When this group completed the feasibility study, we had an extremely --

(End tape 1-A.)

MS. LEWIS: -- interactive all-day meeting with our PPDC working group and also a fair amount of interest on industry side and just the general public attended. So, it was a long day, it was about 9:00 to 4:00, but extremely informative.

The purpose of holding this meeting with the work group was to go over the purpose of what we did and how we structured the study, and then we decided let's pick a sample case from a conventional -- an antimicrobial and a biological. We'll blind the case so that the chemical is not named, but ahead of time, we gave out enough information so they knew the use patterns, the risk picture, the hazard picture, last risk assessment and what it had covered.

What we thought we would do is have the work group actually go through the same sort of thought process that we did and say, here's what

we know. We know what our state of the art is today on policy and science. What do you think needs to happen?

At the end of the day, we also presented aggregate findings, and what we had presented as well was a time line, which you'll see, that highlights major science and policy changes since 1984. So, if you knew that the last risk assessment was done ten years ago, let's say, and you looked at this time line, you may then have a better handle of knowing what data needs or new risk assessments are needed. Next.

So, we started out with this concept, once we gathered our baseline information, and we asked ourselves, what do we know? What do we need to know? And how important is the value of that new information? As we're going through this with the 28 cases, we felt you could end up in three possible outcomes. Our last risk assessments that we had completed are adequate and still meet our safety finding.

This is what's been referred to in the past as easy off ramp, so that no added risk assessment is needed.

The second possibility is we don't need any new data to conduct new risk assessments, but new risk assessments are needed from the last time they were conducted.

And the third and more complex situation is that new data are needed to conduct new risk assessments. Next.

I also want to say what the feasibility study didn't do because of our time constraints. There were no consultations with industry or stakeholders prior to conducting the study. We didn't look at usage or poundage reports. We didn't search open literature or consult with other government agencies that may be involved. We did not conduct new risk assessments, we merely identified those assessments that would have to be done, nor did we call in new data. This feasibility study really was for illustrative purposes to show us, does our

system work?

Attached is a slide, I don't plan to really go over it in detail, but it's in your package, which highlights some of the major changes, and you may want to keep this handy as I go through the next case or two.

We also have a two-page, very detailed analysis of all the changes that happened since 1984 as well.

So, moving on, in that all-day meeting in September, we thought if we were going to work with this work group, we would start with something that was probably -- had few issues to deal with. So, our first case study that was presented was a conventional herbicide used on cereal. It was first registered in the late 1980s, so that's what drove the index date. It was a new AI post-1984.

This is a particular chemical that has had no new uses added since the initial registration, although, because of what we're doing under the Food Quality Protection Act, we

had recently re-assessed the tolerances under FQPA. In fact, very recently. And just to note, that the last risk assessment for environmental fate and effects was done at the time of initial registration in the 1980s.

So, we had the group work through the issues, and what was concluded was that an occupational risk assessment would be probably required, because how we did things in the late eighties on worker is different from how we do things today. We're looking at different end points.

However, no new assessment would be needed for dietary, drinking water. There were no residentials. So, the FQPA finding was adequate and stood, but it was possible that a worker -- new worker assessment was needed.

If you would go back and look at that chart of what has changed, you will notice when we registered compounds in the late eighties, we did a hazard assessment only on environmental fate and effects. What we do today, and it

started sort of in the mid-1990s, is now we do a complete risk assessment with risk quotients. So, in this particular case, we would need to do a full environmental fate and effects risk assessment. We have all the data needed.

So, if you were sort of binning this chemical, it would come out in the doesn't need new data but new risk assessments are needed.

If we can move on to case number two, this is a pheromone that was registered in the late seventies and then actually re-registered in the 1990s. The pheromone was used and always used in a trap at very low rates and very low toxicity. There were no residues on food, nor is it applied directly to food. So, this one we're able to work through rather rapidly, and the decision was last risk assessment stands, it's still valid, data requirements are satisfied. So, this would be an easy off ramp.

Then at the end of the day, the second half, we saved our more complex case for antimicrobials. We selected the case study for

an antimicrobial that was registered in the mid-eighties and had been re-registered in the mid-nineties. This was pre-Food Quality Protection Act, though.

It has multiple uses with various routes of exposure, including possible dietary. There's indirect food uses. There's some FDA-409 clearances, indoor uses, outdoor uses. So, multiple routes of exposure.

After lengthy debate and discussion, the group I would say did come to the conclusion of what risk assessments were needed. This is one, as I said, that's much more complex. In essence, a whole new human health risk assessment would be required, including dietary, residential, occupational, drinking water and aggregate. The last assessment was done pre-Food Quality Protection Act.

Again, a complete ecological risk assessment is needed as well. So, this is one where it would be at the end where you'd need new -- we also had data needs. So, this is one

that would come out in the category of data is required to conduct a risk assessment, and new risk assessments are needed.

So, to give you a sense -- okay, I'm sorry, go ahead. I missed that.

I thought we had an awful lot of background information in this all-day meeting, and I have this web site listed so that if you're really interested to have more details on all these case studies, I boiled down in a very short period of time what we spent roughly a full day discussing. There's presentations posted on this web site. Thanks. Next.

So, to give you a sense of where did we fall out in an aggregate sense, doing these 28 illustrative cases, why don't we start with conventional chemicals first. So, you see there's three sort of boxes listed. No new assessments needed, the majority, vast majority, between 80 and 91 percent, fell out that no new risk assessments were needed. The existing risk assessments were adequate for our safety

finding.

During -- these chemicals had recently gone through Food Quality Protection Act tolerance reassessments, and the work had just recently been done. So, as you can see, the vast majority, no new risk assessments needed.

There were no cases where we even needed data. That middle column where you see 8. -- 8 to 16 or 8 to 17 is really that worker study.

It's a little bit different on the environmental fate side. Where we came out on the 12 cases for conventionals was there's possibly one that wouldn't require any environmental fate assessment, and that had to do with classification of use. If it truly was an indoor use, there would be no endangered species or risk assessment needed. But between a quarter and a third required new risk assessments but no data, and as you can see, between a half and three-quarters required data and new risk assessments.

Now, what's important to keep in mind is is that time line of when the Agency went to combined risk assessments and what we're doing now with endangered species.

On the antimicrobial front, we also have a different picture. We selected six cases, and there was one of the six that would have -- the existing risk assessment wouldn't require any additional work, so an easy off. The remaining, over 80 percent, require new risk assessments and new data.

This doesn't always mean it requires both human health or environmental fate. I believe three of the six required both human health and environmental fate, and then the other two needed one or the other. So, on antimicrobials, significant new risk assessments.

On the bio-pesticides, the ten cases, over three-quarters were existing risk assessments were adequate and stood. As you can see, less than 20 percent requiring new risk

assessment or new data. So, depending on the type of chemical you have and when it was last re-assessed, especially for Food Quality Protection Act, that potentially may make a difference in reregistration or registration review. Next.

So, just to summarize our general findings, once we ran these 28 cases through our design, we felt the process is feasible. We were able to make decisions. The work group was able to make conclusions on risk assessments once we explained our process. It's important to note we're still -- this process isn't set in stone. We're still working on the process. It's a work in progress.

The need for consultation was really highlighted because we were unable to do that given our time constraints. I think we could have had a much broader input by stakeholders and industries in meetings early on. So, this really does highlight the critical need for public participation and consultation.

It quickly brought home some of our programmatic needs for managing information and technology. For these 28 cases, you have the 80/20 rule, and we probably spent 80 percent of the time collating and collecting the information and roughly 20 percent of the time, once we had that information, making our scientific finding. So, we have some work to do on our IT front.

It also helped identify regulatory issues, especially on labeling, labeling clarification needs. What is appropriate on a label? What do terminologies mean on labels? And it identified some additional tweaks in our process design.

The meetings I think were extremely beneficial when we had the risk manager and risk assessor meet both before the sort of assessment was done and after. So, communication, the need for communication, was really key.

That concludes the discussion on the feasibility. Again, I'd point you to the web

site that is listed if you'd like some more background information, and I will hand it over to Erik Olson to talk about public participation.

MR. OLSON: Good morning. I'm going to talk a little bit about public participation. This -- George Wichterman, who's with the Lee County Mosquito Control District I think is busy in Florida spraying for mosquitos, so he's not here, but I will summarize what is both sort of a philosophical approach to public participation in this process and some of our more specific recommendations.

We suggested that public participation be viewed sort of in the context of long-standing EPA policy guidance, including the administrator's famous fish bowl memo from a while ago in which it was recommended, that EPA provide the fullest possible public participation that EPA employees remain open and accessible to all points of view, and that they make affirmative steps to try to do outreach to

seek a broad set of public participation, and also, that no one group would get unique or special access to the decision-makers.

That philosophy is embodied, we think, in the special review regulations, which specifically require basically almost exactly what the fish bowl memo says. Some of the language is laid out in slides 25 and 26. I won't read it to you, but our recommendation is basically that that kind of approach be embodied in these registration review regulations that the Agency is going to be proposing, and the rules are embodied in Section 154.27 and some of the rules around there.

The importance of public participation from our perspective is, of course, it makes EPA's life a little more difficult, and I will note that the presentation you just heard, EPA didn't do the public participation, so it's not necessarily going to be quite as smooth as obviously what can be done in a month reviewing a handful of pesticides, but we think it's

important, both because it provides an identification of issues very early in the process, so there aren't big surprises later, so the public and stakeholders can have a chance to give some input, and also, that surprises are not in EPA's interests or in the public's interests, that it's better to have early identification of the issues so that we don't have blow-ups late in the process.

Among the points where we thought it was important, public notice of the schedules that when EPA comes up with a schedule of when it's going to review chemicals, that that be issued to the public so people know what to expect and when; that when the review is initiated, the public be notified; and one issue that we discussed at some length and didn't reach consensus on is at what point should EPA be issuing data call-ins or information requests. Everybody agreed that as early as possible. The question is really, how early? The thing to avoid, at least in our perspective,

is that EPA gets to the point where it's supposed to be making a decision and says, oh, golly, we had these three studies that haven't come in yet, and then asks for them, which delays things. So, the idea is to try to identify information needs as early as possible so that we're not playing catch-up when the decision is being made.

So, some of us suggested two years in advance, that the Agency try to look at its files and decide whether it needs studies, and others thought that that wasn't realistic. We'll talk about that a little more later.

Obviously, tiered studies, which are studies where the first initial study says, well, there could be a problem here, we need to do the next round of tests. You're not necessarily going to be able to identify those well in advance, because you may not have the results yet, and also, there may be other studies that you just can't predict are necessary.

Some of the other specific points where we thought public participation would make sense is in smart meetings, which are sort of the first early meetings that EPA sometimes has with registrants now, that those be more open and available to everybody basically to participate in and that early notification of other agencies, in particular in addition to registrants and workers and environmental groups, but the Centers for Disease Control, including NIOSH -- and I'm sorry, we didn't include NIOSH in the slide, but that would be an important aspect of it, as well as NCEH, the National Center for Environmental Health, Fish & Wildlife Service and USDA and so on, just to get everybody up to speed at the same time.

We also had a recommendation that the actual decision document, and this should be obvious, I think, go out to some kind of public comment. So, if the Agency decides either there needs to be review -- there needs to be additional review or makes a final decision on

the chemical as part of registration review, that that decision be put out for public comment.

We wanted to identify -- we recognized that the ultimate regulatory decisions, of course, are EPA's and that the registrants may make their own decisions for business reasons to withdraw a chemical or support for it, but we thought that it's important that EPA bring in other federal agencies as required by law in order to make sure that everybody has a seat at the table in this process.

So, in the -- this is -- George feels very strongly about this, so I will put it forward, that he wants to emphasize that especially with public health pesticides, that EPA bring in CDC when it's making decisions about public health pesticides before the decision is made. You'll see he quotes Section 4(n) of FIFRA, which is directly relevant to reregistration. There aren't specific requirements for registration review, but he

thinks that this process would make sense for registration review. I'm not going to read all of the statutory language, but it's pretty self-explanatory.

Procedures for registration review, we think that it -- this was, I think, a fairly widely agreed-upon view, that EPA really ought to be moving in the direction of expanding its edocket, it's electronic docket, so everybody has access to the information on the web, and that that ought to be sort of a general principle, that essentially we move toward the electronic approach. It's probably going to require some IT investment for the Agency, but I think every outside group thought that that was very important to do.

We also -- in there, we're citing the docket requirements in the special review regulations, which we think could be a model for what would go into the docket and probably should be incorporated.

The docket should also include

information on what data call-ins have been issued and what studies are outstanding right now. At least for outside groups, it's very difficult to learn that, and it would be quite helpful just to have a publicly accessible data point so that we would know what studies are outstanding, what studies have been done, and I think ultimately it would be helpful to the Agency, as of turnover and everything else, to have a central location where that information is available.

We also, again, think that it really ought to be open to everyone, that no one party should get a special opportunity to participate.

An additional issue that we discussed at some length was how to make sure that those -- that there is procedural protection for everyone. Again, we suggested that EPA perhaps model this new regulation on the special review rules that make sure that there is sort of this broad and open process.

In addition, we think it's important to

notify all of the stakeholders and provide an opportunity to comment on EPA decisions, and again, cited some of the regulations on that point that are extant.

As far as registration review being a safety net, this is sort of our bottom line, and we feel this is very important. We haven't really gotten around to talking about this, frankly. Everybody agrees it's a safety net, but what does that mean and what is the process if a new risk is identified?

So, for example, if there is a new study that comes out on endocrine disrupters or endangered species concerns or an open literature study that suggests there's a problem, we all agree we don't want to wait for ten years, perhaps, for the EPA to consider that, but we haven't really agreed what it means to say it's only a safety net and that there needs to be some other process where there's a problem for the chemical. So, I would hope that we'll have some discussion of that either today

or in the work group as time moves forward.

Basically, I think we also are recommending that these detailed procedural requirements, although they're very important, shouldn't block EPA from doing its job if it identifies a significant problem. Obviously you want some public participation, but you don't want to impede the Agency from moving forward if there's a significant problem.

So, that's basically how far we got.

MR. ELLENBERGER: We would like to open it up for discussion, questions, comments.

MR. JONES: Jay, can I just ask Erik a question? Erik -- and it's also, I guess, for James. Do your -- the recommendations that you just put forward, do they reflect an agreement with you and George of recommendations, or do you think they represent the broader work group's recommendations to the PPDC?

MR. OLSON: To be honest, what we did was we agreed that George and I would put this together, and we emailed it out a couple days

ago and took some comments on it, but I wouldn't say that every word of every slide has been agreed to every single person in the group, because, you know, realistically people got maybe two days to comment on it. So, you know, there will probably be more discussion I assume of these issues.

UNIDENTIFIED FEMALE: Bill?

BILL: A little over a year ago, the Agency published a notice in the Federal Register of its intent to form a bio-ethics advisory committee. In looking at the flow chart of the -- in the seventh slide of the first part of the presentation where it says, "Registrant provides data, agency reviews," it seems to me that there is -- that that would be an opportunity for that committee to interact in the decision-making process.

To my knowledge, the formation of that committee is stalled. Is that the case? If not, how does the Agency envision that committee participating in this process?

MR. JONES: The committee as far as I know has yet to be activated. It's being run out of RSAB office, which is in the Office of Research and Development. I'm not familiar with the specifics as to why it hasn't engaged, and I don't think we've given much thought to what its potential role in registration review has been, unless we had an issue specifically in a chemical that raised bio-ethical issues.

MR. ELLENBERGER: Any other questions?

UNIDENTIFIED FEMALE: Just to clarify George's -- because I know what he was referring to in this with regard to public health pesticides. Because public health pesticides tend to be minor uses, in some cases because the market is very small, a registrant may elect not to support the continued registration or supply the data, and he wanted to ensure that as was the case with reregistration, that when we go into registration review, that to support public health pesticides, that before a final decision was made not to support a registration or to

cancel a public health pesticide, that the Center for Disease Control, as was designated for reregistration, be engaged to ensure that if that product is necessary for the protection of public health, that it be supported even if there is not an economic incentive or an economic justification for the registrant to do so.

MR. JONES: Gary, and then Shelley.

GARY: I have a question on your slide 20 for just a second, if you want to get to that.

I thought the case studies were quite interesting. I just have a question on the aggregate consults. When you talk about no new assessments and so on, are you talking about percentage of the studies themselves, or are you talking about percentage of the cases? Like if you have 76 percent of ten studies, what does that mean exactly?

MS. LEWIS: T. J.?

MR. WYATT: I'm T. J. Wyatt. I'm with

the Economic Analysis Branch of EPA.

The reason that those particular studies don't round up to what seems like 10 percent is that within the bio-pesticides, we actually have another two categories, bio-chemicals and microbials, and we looked at five each from those categories, but they aren't equally split in the number of chemical cases that are registered. So, that's a weighted average given the relative percentages in those -- of those two categories.

So, these percentages are of the cases in the feasibility study, not the individual AIs.

GARY: Thank you.

MR. JONES: Shelley?

SHELLEY: I just wanted to ask a clarifying question. In the presentation, one of the speakers mentioned that there was a difference between how occupational risk assessments are done in the eighties from now. Could you maybe just highlight, you know, what

exactly you're talking about?

MS. LEWIS: Sure. If we go back to the handout, in the mid-nineties, we started selecting acute and subchronic end points, whereas before they had been more chronic end points of working -- for worker risk. That's one example.

We also have a lot more data now from task forces that have to do with transfer coefficients when we're looking at re-entry intervals and how we set re-entry intervals.

Ray, do you -- Ray Kent may have some more specifics.

MR. KENT: Actually, you have covered it pretty well.

MS. LEWIS: Okay.

SHELLEY: Thank you.

MR. JONES: Caroline?

CAROLINE: Let me see if I have this right first. On the slide 20, there were few chemicals in that group that needed new assessments because they had been evaluated

for -- and had an FQPA finding made. You may not have this data today, but I'd like to know kind of how many of the chemicals that were assessed and evaluated and have an FQPA finding actually required new data. And the reason I'd like to know that is we're looking at for a 1984 chemical 20 years, and I'd like to know whether we've actually advanced in looking for new data about health in that 20 years.

MS. LEWIS: So, is your question did we make new data before we could make the finding?

CAROLINE: Yeah, what percentage of those chemicals.

MS. LEWIS: We don't have that, I believe, but we can look into that.

CAROLINE: But you see what I'm getting at?

MS. LEWIS: I understand, what was necessary to get them to the FQPA.

CAROLINE: Right, because I mean outwardly, that's a perfectly reasonable explanation for why that's the case, but I'd

just like to know about how far we're advancing the ball on looking at health effects.

MR. JONES: Pat?

PAT: I guess another question for Susan, the 83 percent, the five out of six antimicrobials that would require more data, more risk assessment, obviously there's a pretty wide discrepancy between that group and the rest of what you looked at.

Were there certain characteristics of the data that's present for those chemicals that set them apart? I mean, what were the --

(End tape 1-B.)

MS. LEWIS: -- who have -- who have the details on this.

UNIDENTIFIED FEMALE: You have to go to the mic.

MS. SCHMIEGEL: Hi, I'm Debbie Schmiegel of the Antimicrobials Division.

So, I think some of the characteristics were -- let me just make sure I understand the question. It's why -- what was unique about the

antimicrobial pesticides that triggered additional risk assessment?

Well, a lot's changed in antimicrobials. For example, a lot of the chemicals had indirect food uses, which were previously cleared by FDA, and we didn't previously assess those. So, now, that would be something that we do have to look at under FQPA.

Also, a number of the chemicals had cleaning uses, things in residential settings that we previously did not have SOPs for and that we would look at today, but that -- in the mid-nineties or late eighties, we typically did not consider those as part of looking at aggregate assessment, for example, for children.

Also, some of them had outdoor uses, and we deferred to Office of Water typically in the mid-eighties and early nineties, and now that -- we would typically do a risk assessment, looking at ecological risks, looking at risk quotients and levels of concern.

So, that just kind of gives you a

flavor of what we did have in our existing files versus what we would do today.

Any follow-up?

UNIDENTIFIED MALE: Thank you.

MR. JONES: Erik?

ERIK: Yeah, I just wanted to ask what process you're considering, Jim, for things that may -- where there is new data, where some concern does arise, 6-A-2 data comes in or open literature data comes in or there's an endangered species concern raised by Fish & Wildlife Service or whatever, something that's sort of a hot issue.

To date, you know, there's been special review, but that takes a long time. Has the Agency thought about or are you going to delegate to our committee or what are you thinking about how you really make this a safety net and not end up having the safety net basically having to catch everything?

MR. JONES: That issue is one that we currently have before us and struggle with. You

know, you come up with the schedules for your old chemicals program, and you know, you've got to get 500 of them done in ten years or 15 years, and you come up with a schedule, and then something comes to your attention that makes you pause, or if not, it's a red flag that is -- clearly requires some attention, and so I think that the approach that we have to date have, which is that those things get taken out and basically brought up to the top of the queue, is the approach that we plan on using in registration review.

It's the same issue we deal with in reregistration and tolerance reassessment, and we will bring those things to give them higher priority, take them out of their line and queue. We haven't actually put them into special review for a number of years. We've instead just brought them to the top of the queue in our reregistration work, and I expect that that is what we would do. It's, frankly, how we've described it in the preamble of this rule,

because I thought that that was advice we were getting from the PPDC work group, that you really had to have some way of picking up things that just brought information to your attention, that raised a concern.

ERIK: Well, I guess I think it would be worth giving a little thought to how to avoid making that completely ad hoc, that you know, if there is some significant trigger, that at some level, you know, some decisions are going to be made on that in a fairly timely fashion, and it's a difficult issue, I recognize, but I think it's perhaps the most important issue that we may face, because we're talking about a 15-year time line, and everybody agrees that if you get a hot problem, you're not going to delay for another 10 or 15 years, but I'm not sure we've really thought through, at least our group didn't, how you deal with that situation.

Right now, it does seem somewhat ad hoc, and maybe that's just from the outside, but it seems like something that's an important

issue that might bear some discussion.

MR. JONES: (Inaudible.)

UNIDENTIFIED FEMALE: I could see that perhaps it might be helpful to set up some particular guidelines in addition to the ones that maybe already exist, but I certainly wouldn't want to lock the Agency into not having the flexibility to in another ten years find something else that needs their immediate attention. So, I think you would have to be really careful in how you set those.

MR. JONES: Oh, I'm sorry, Shelley.

SHELLEY: I just wanted to actually follow up on that same point. Can you give us some examples of ones that went to the top of the queue? If you don't want to name the chemical, like the reason or, you know, some sense of your criteria of what brought something to the top of the queue?

MR. JONES: Incident data came in, a study came in that showed results that were surprising and just weren't expected and changed

our understanding of the hazard. Those are the two things I think that most likely in our experience have brought something right to the top of the queue.

SHELLEY: Some could you estimate like how frequently this occurs? I mean, is this like a one in a hundred, a one in ten?

MR. JONES: It happens at least once a year, I would say. I don't know if that gives you a -- there's no denominator that I know, but it's not that infrequently.

Pat, did you have another comment?

PAT: I'm sorry.

MR. JONES: Perhaps we could do a little summarizing around this part before we move on to the data needs section. One of the things that -- well, there were two things that I think that the work group should think about working on further, maybe three. Three actually.

One is this issue of how the Agency deals with when it actually needs new data, the

DCI issue, and I think it would actually be worthwhile to, again, do it in the context of an example, even if it's a made-up example, and literally play it through in the work group to see if everyone sort of has the same sense of, well, how would it play out if the Agency comes to the conclusion it needs four or five studies to bring a chemical into compliance with today's standards, and see if everyone's comfortable with the way you all see it playing out. So, again, sort of doing -- working through an example around that.

There were a number of issues in the presentation, Erik and George's presentation, around public participation, that I think it would be worthwhile for the work group to spend a little more time to see how much consensus there is around that. It wouldn't surprise me if there's consensus over three-quarters of it but maybe not all of it, and it really would be helpful for us to know just how broad the consensus around those recommendations is.

That could be quite helpful, the more consensus there is on issues, the easier it becomes for us and the fewer choices that we need to make. Obviously we need to make a choice whether to accept it, but when I face consensus with broad stakeholders, I'm inclined to accept them. So, I think it would be useful to spend a little more time on just how broad is the consensus around that.

I think I implicitly answered exactly what our current plan is, I think, around when something hot comes to our attention, what are we going to do. I think that we would benefit from having the work group spend a little more time talking about that, and the answer is right now, we're approaching it as we are identifying it in the preamble with what our intention would be if we get information that leads us to believe something should be taken out of the order.

We are not intending at this point to put something in the regulation. So, you right

now know what the general plan is. I think having the work group spend a little more time with that knowledge to see if a consensus can come out of that as to whether or not that approach is the approach you would recommend or if you would recommend a different one. Again, if there isn't a consensus -- if there is, it would be useful to know, though, what the -- those are the three things I thought that this part of our work group could spend some focused time on in the next three months. I think it would be important for it to be in that time frame.

That's sort of what I had as follow-up around that. Was there -- okay, why don't we move on to the next part of this presentation.

MR. ELLENBERGER: Okay, we will move on. Julie Spagnoli from Bayer is going to make a presentation on thoughts that she, Ray McAllister from CropLife and Sue Crescenzi from Steptoe & Johnson have on dealing with refining data requirements.

Julie?

MS. SPAGNOLI: Okay, similar to the public participation process, these were kind of assignments made to a subgroup of the work group that we tried to come up with I guess recommendations based on the previous discussions that the work group had had and identifying any issues, but not -- because of timing, as Erik said, we kind of shared these with the work group, but it's not necessarily that there's a full consensus yet, and Erik indicated with -- you know, as far as what the timing was for supplying new data, we tried to approach it from what we saw as the most practical standpoint, but we really haven't totally vetted or come to a consensus on this.

But what -- first we looked at -- you know, tried to think about and identify what types of data requirements might there be in looking at any particular case or active ingredient, and one would be if there was an actual new data guideline requirement that

was -- you know, hadn't previously been requested of that chemical or any other chemical, data that might be -- that had not been requested previously for that chemical but now was required of chemicals with similar uses or similar products.

There could be data needs that were triggered by a particular concern but that had not been requested previously, and then there could be the case where data had been requested but had not yet been supplied. So, we tried to look at what were the possible types of data needs that there might be.

The first being, you know, a new data -- a new guideline requirement, this would be if a particular piece of data or a study was needed for a chemical that had never been requested before and hadn't been requested of any chemicals, and if -- the way we looked at this is that if a new guideline study was applicable to support the registration of all active ingredients meeting a certain criteria,

then a DCI should be issued for all of those active ingredients.

For example, if it was decided that, you know, all products registered for use on golf courses needed some particular study, then a DCI should be issued to all products registered for use on golf courses. You know, that registration review should not be used a is the mechanism for implementation of a new data requirement, that when a new data need was identified based on a certain criteria, it should be requested of all chemicals and not used -- not called in via registration review.

If such data are necessary, though, to conduct a new risk assessment in the course of registration review, they have to be submitted before that registration review can be completed. So, given, you know, where -- when the data is called in, what the schedule is for submission of the data and when a chemical is -- you know, comes up for registration review, it could affect the timing of the completion of

registration review.

The next one would be data that were not previously requested but now are determined to be necessary. If -- in the -- in that initial -- if you remember that flow chart where if it's determined that a new risk assessment is necessary, the next question that is asked, are all -- are all the data that are necessary to conduct that risk assessment available, and if in that process it's determined that particular data are necessary to conduct the new risk assessment, then at that point the Agency would have to issue a DCI for that data. Then, of course, the final assessment can only be completed after the submission of the data.

If it's determined that these data are only confirmatory, that they're really not necessary for a risk assessment, but they are necessary to bring a chemical up to all current standards, then they could be issued as a DCI at the completion of registration review. And an example of this would be if an additional

residue study is needed just to bring a product up to full guideline requirements, although that data might not be necessary to make a decision or to conduct a risk assessment. It would just be confirmatory data.

There could be in the course of the registration review, if they're looking -- in that initial assessment, when they're reviewing incident data, that it could -- concern could be raised by looking at incident data that could trigger the need for actual data to conduct a risk assessment to the -- for that particular risk. You know, if there was indications that there were a number of fish kills or something, there may be some additional data necessary in order to really assess that risk.

So, if those data needs are -- when those data needs are determined, then again, a DCI would have to issued and then the risk assessment completed for that particular risk when the data are submitted and reviewed.

The last category would be data that

had been previously requested, and this could have been, you know, on the basis of a previous DCI. If the waiver request was pending to that DCI, if the registrant had requested a waiver from a DCI and that decision was still pending, then the decision -- final decision on that waiver request would have to be part of that initiation of the registration review. The Agency would have to determine, are these data truly necessary or not and either grant the waiver or request the data.

There also could be the case where if a generic data exemption was claimed by formulators, but then the basic registrant elected not to support a particular use, then the EPA must inform those formulators, and they would have to decide if they are going to support the use themselves and supply the necessary data.

And then again, the data generation -- there could be data generation that's still under process under a DCI. This would be, you

know, if a DCI had been issued a year previous to the initiation of registration review, the data may be in process but not yet submitted. If those data are necessary to conduct the new assessment, then the registration review would be completed after the data were submitted.

And again, you know, we're looking at this from the standpoint of the fact that there's -- if there's going to be 50 chemicals a year for -- that registration review will be initiated for, as, you know, Susan had indicated and from the feasibility study, we know that not all 50 are going to have the exact same set of circumstances. Not all 50 are going to necessarily need new assessments or new data.

And so, trying to look at the -- you know, the flexibility of the process and, you know, if data are necessary, what types of data might be necessary, and the best way of, you know, timing that, recognizing that, you know, if 50 chemicals are initiated in a given year, not all 50 may necessarily be completed on the

exact same schedule, and we just have to try to build in the flexibility into the process and be most efficient.

If, you know, two years from the review is initiated they have to go back and review, then really you're actually starting the review at that point. So, again, it is really not possible to initiate the review before -- two years before you initiate the review.

So, that's, you know, what we kind of tried to look at from a practical standpoint of how do we most efficiently get the data necessary, and I think the key point was is that we don't want registration review to be the sole means of calling in or collecting data. If data are necessary at any point in the registration process, then the data should be -- you know, if a special issue is identified, then the data can be asked for at that point, but this is not the sole mechanism for requiring either new or previously requested data.

UNIDENTIFIED FEMALE: Anyone have

questions from (inaudible)?

MR. JONES: Questions? Allen?

ALLEN: This may be more a manifestation of my own ignorance about this, but I'm wondering whether there's a requirement on the part of a registrant or public health officials or anyone else who might gain access to information that would adversely affect the registration process, to turn this information over to the Agency. It sounds to me like if the -- one of the mechanisms by which the Agency gets this information is through the data call-in process, but it seems to put the burden of responsibility in a different direction, more on the Agency has to ask for it rather than being a compulsion on the part of others to divulge this as it occurs.

MR. JONES: The statute does provide that if the registrants have information that indicates potential adverse effects, they are required to submit that to the Agency. That's part of the statutory and our regulatory

program.

Erik?

ERIK: Yeah, I just want to pick up on an issue Julie raised toward the end of her presentation which we wrestled with in the work group and I think is worth broader discussion of, which is, of course, you can't initiate a review before you can initiate a review or whatever, but the question is really how do we avoid the pitfall that the Agency often finds itself falling into, which is that it gets to the point of reviewing something and has to make decisions, and it turns out that if it had done sort of a preliminary review of its files two years earlier, it could have said, oh, these three DCIs haven't been answered or this data isn't up to date and could have made that request earlier so that when the decision point comes, that all the data is collected.

So, it's a difficult issue that we did wrestle with, and I'm not sure we came to consensus on it, but at least from our

perspective, we'd like to avoid that pitfall. So, if we're talking about every chemical being reviewed 15 years after its last decision, that we not wait until 15 years after its last decision to review the file and say, ah-ha, these three DCIs haven't been answered and these other new guidelines haven't been complied with, and therefore, we're going to ask you to submit the data, and it's going to be two or three more years later.

So, I guess what we were urging is that there be some kind of built-in process in these rules that a couple years before the decision point is scheduled, which would be 15 years after the last major decision, that there be some kind of preliminary file review to make a decision as to whether there is new data or data that should have been in the file that isn't there. That was the point that was trying to make in my earlier presentation.

I'm not clear on whether, Julie, you are disagreeing with that approach or maybe you

can amplify upon what you were -- what you were trying to say in that last slide.

MS. SPAGNOLI: Well, I think that, you know, if you're going to go back and do a thorough review of all the data, that's really built into the initial process, that it's -- I think that we -- I don't know if we can pull that little flow chart up. Which one was that?

UNIDENTIFIED MALE: The one on page 20?

MS. SPAGNOLI: Yeah, whatever.

UNIDENTIFIED MALE: Slide 7.

MS. SPAGNOLI: Seven, yeah.

I think, you know, it's at that point that the decision's made that a new assessment's required, and then the next question is is do we have all the data to make that assessment? If the answer is no, then we have to -- you know, the registrant has to provide that data. There's really -- if you -- that's where that decision would be made.

Now, I think to your point, if there's been a new guideline requirement that's just not

been complied with, if there's some way that that can be identified earlier, I guess that's something we can -- we can look at, or if a DC -- you know, if a DCI had been issued but just not complied with, I guess that's something we can further discuss.

MR. JONES: I'm going to go out of order with Caroline, who seems to want to make a point to this point.

CAROLINE: Yeah, I think what we're talking about is inventory. I mean, we can't do a qualitative assessment two years in advance and say we've got a study but it's not very good, because that's what the review is, but you're really talking about an inventory. So, what you could do is have a system set up where all the studies are online and reported and go back and run a -- you know, run a model and see what's missing, see who's missing studies. That doesn't seem to me to be that complicated.

MR. JONES: You know, my understanding -- I think the way that right now

that the rule plans on -- not the rule, but the program plans on addressing that is the whole idea of pulling together the baseline, all of the information that we think is relevant to that chemical and making that available for all stakeholders to look at and say, whoa, whoa, whoa, you missed this and you missed that.

Whether that is foolproof or not, I doubt it will be foolproof, but I think that that's the current thinking in terms of how we can work to assure that everything we have or should have is available for people to look at first before we start going down the road here.

CAROLINE: But that's, again, part of the review itself. What I'm suggesting is that you could have some kind of program that you run -- you could run it any time and just see what chemicals are out there that are missing studies that you've required.

UNIDENTIFIED MALE: Carol, I think the opportunity that we have in this program as we're designing it is when you -- when we pull

the information together to put in a public file, how much looking do we do at that information? Do we do a preliminary kind of screening issue, if you will, of looking for obvious data gaps or cases where we've called in data and the data haven't come in, contacting a registrant, are you on schedule to submit it by date X when it's due, et cetera, et cetera, and that can happen -- you know, we can -- we can construct that schedule to do that process, whether it's a year in advance, two years in advance, whatever might be the right mix, so that we get as much of that data need identification up front early rather than closer to the scheduled completion date.

CAROLINE: Yeah, well, what I'm suggesting is rather than do that chemical by chemical, which is so much of what you do in this damn program, is that you can do a program that will do that for you and you don't even have to look at the chemical if the studies are missing. Again, you can't do an evaluation of

the studies, but --

UNIDENTIFIED MALE: I am hearing some very generic advice about how we track DCIs. I hear you. It's not specific to registration review. It's very relevant to it, but it's not exclusively --

CAROLINE: Exactly.

UNIDENTIFIED MALE: -- associated with it.

ERIK: Yeah, I would like to follow up on that. This sort of feeds into the recommendation for an e-docket. You know, if there were a sort of publicly accessible tracking system of DCIs and information requests, the Agency could run its own report on this routinely, and it would be on your desk monthly or whatever that would tell you exactly what DCIs are outstanding, what issues are outstanding, but that -- and I think that is important.

The idea of the registration review as a safety net would be that although you would

have that routine, programmatic thing built in, that at some point there be a prescreen well before the decision point is scheduled. So, if the last time you did a major review of chemical X was in 2000, you don't want to wait until 2015 to go into your files and decide whether there are a bunch of studies that are missing or just blatantly inadequate or whatever.

So, you know, I think it is a balancing act, but you want to have, we think at least, a couple years before the decision point, somebody to go into the files and pull that information together and do that prescreen and decide, well, are there some obvious deficiencies in the database that we know we're going to need, and you know, you may miss things. Obviously if you don't read every word of the study and comprehensively peer-review everything, you're not going to get everything, but if there are sort of sore thumbs that are sticking out, that that be identified well in advance.

And again, this is a safety net. You

don't want to supersede DCI deadlines and noncompliance with DCI deadlines to wait for ten years.

MR. JONES: Shawny?

SHAWNY: Yeah, just to dovetail on what Erik was just saying, I think that it would also be important through the e-docket process also, you know, just opening up this a little bit more to stakeholders and a little bit earlier, that you would also hear different perspectives on what might be confirmatory information versus, as Julie was pointing out, these two categories of what might be confirmatory, and therefore shouldn't hold up the risk assessment process, versus data necessary to complete a risk assessment, and of course, I think that there's different opinions out there about what data should hold up a risk assessment and which should not. So, again, that would be a good way to get those kinds of opinions.

MR. JONES: Troy?

TROY: Thank you. A clarifying

question to Julie's slide 39. There are four bullet points there, but only one explicitly mentions the new guideline. I just wanted to clarify that the other scenarios for data requests would be based on guideline studies as opposed to come to us with a protocol, we'll let you know if it flies.

MS. SPAGNOLI: Well, which I really didn't elaborate on. I think we were kind of just thinking about what were the types of data. I mean, I think one of the issues that's frequently come up in the discussions with the work group is the need for the promulgation of Part 158 to have -- to know what are all the data requirements. I mean, I think that comes up just about every time we get together and talk.

So, I think essentially it is -- for the most part, I think we are looking at what is a guideline study. You know, if it's determined that, you know, a fish toxicity study is necessary, it would be the guideline study. I

don't -- you know, I suppose if there was a data need triggered by a particular concern, depending on what that concern is, it could be some kind of specialized data, but we didn't, you know, really elaborate on it. We just kind of thought about what are the different kinds of data that might, you know, be necessary as part of this process.

When they got to the point of looking at if we need to do a new risk assessment, are the data available? What could be the possibility? So, that's really how we looked at it.

TROY: Thank you.

MR. JONES: Shelley.

SHELLEY: Well, I would think that there is some process or you should certainly have a process of tracking your DCIs and making sure that stuff is on time.

What I was thinking about is the kinds of other opportunities you would have to make sure you have all the data you will really need,

and a couple opportunities that seem to come to my mind, I guess I would like to draw some lessons, for example, from the requirement that certain OPs or all OPs -- I don't know exactly what you ended up doing -- have the developmental neurotoxicity study, and that was something that I think emerged out of your review of which pesticides are in a cumulative risk group.

So, that might be an opportunity to say, well, if we're going to look at, you know -- and that's a relatively -- I don't know if early or late, but in the scheme of how you actually did it, it was before you had completed the individual risk assessments on individual OPs, you had made a determination about this risk group, and that seemed to trigger the notion that as a group, and I guess Julie was talking about this, too, that the need for requirements, you know, for chemicals of a group, you know, that would be an opportunity to say, well, do we is enough for this whole group,

and that got raised.

Now, you know, I'm an outsider to this process. It seemed like it took a really long time from the time that the need for that type of study arose to the time that it was actually called in. So, it seems like a good opportunity to go back and do like a little case study of your own to say, well, you know, did we really move forward on this as expeditiously as we could?

In the same kind of vein, in terms of new data that's going to come up, I mean, I think that you're looking at that with the new endangered species kind of concerns. As this comes up, you're going to find that a whole number of chemicals are going to be involved, you know, in a particular watershed or habitat or something like that, and it's going to be another opportunity, I would think a little ahead of your making this individual chemical reviews, to say to yourself, do we have all the data we need?

I guess what I'm suggesting is you might look at the processes you already go through for --

(End tape 2-A.)

SHELLEY: -- or FIFRA or whatever and say, you know, what are the time periods in which these kind of data needs might come to the fore as opposed to waiting for individual chemical reviews?

And I guess one other sort of systemic point I would just like to make is that another problem that seems to arise from time to time is that the studies you get just aren't adequate, and so, you know, this is another kind of thing that you have got to have in place, is to, you know, have some kind of review so that the adequacy, you know, or the blatant inadequacy of a study doesn't just come to the fore when you do an individual chemical review.

UNIDENTIFIED FEMALE: Yeah, I actually wanted to ask a clarifying question about the new guideline requirements situation to see

first, I guess, Julie if I understood what you were saying and then -- the way I understood what you were saying is if the Agency decided and had established a new guideline for a new type of requirement and it was required for, say, all pesticides that had food uses or all pesticides that had residential uses or whatever the group was, that we shouldn't wait to impose that requirement one by one by one, as we did registration review, but we should then presumably do it some other way.

And I was curious, if I'm understanding you right, if the group thought about, well, what's the other way if it's not through registration review and how -- and sort of how that might actually impact registration review and other activities, especially if it was across a large number of chemicals, because it was, say, all food uses or something like that. I don't know, did the group spend time talking about that?

MS. SPAGNOLI: Yeah, I mean, we spent

considerable time, I think, saying that registration review should not be the mechanism for imposing new data requirements, and that, again, if a particular new guidelines is -- or a new data requirement is determined for a certain chemical -- you know, all chemicals meeting any particular criteria, that a DCI should be issued for all chemicals meeting that criteria, you know, at the point where it becomes a data requirement, and then, you know, the timing for those -- for -- you know, the submission, whatever it might be, depending on the study, would be the same for all those chemicals, you know, it would be more of just the standard DCI.

If a particular chemical was in the process of registration review at that time and those data are necessary to complete a risk assessment for that chemical, well, then, obviously the completion of that risk assessment will have to be contingent on the submission and review of those data, so that -- but they don't necessarily have to wait -- you know, if

chemical A is in registration review right now and chemical B isn't going to be in registration review for ten years, but they both need that -- you know, if that's a data requirement for both of them that's been determined to be necessary to support their registration, you shouldn't wait -- you know, require it of chemical A at registration review and then wait and require it of chemical B ten years later. That's how we were thinking of it.

UNIDENTIFIED FEMALE: Okay, and then just to follow on, then, does that imply if we impose the data requirement at the same time for the whole group, that you'd also evaluate the data at the same time as opposed to waiting until the -- say for the tenth year or --

MS. SPAGNOLI: I guess it would depend on --

UNIDENTIFIED FEMALE: Did you talk about that?

MS. SPAGNOLI: I would assume that if it's determined those data are necessary to make

a decision on the continued registration of the chemical, then yeah, I would have -- you know, I mean -- I think we're, you know, we're hoping that's not the case that often.

UNIDENTIFIED FEMALE: (Inaudible) new guidelines.

MS. SPAGNOLI: Correct, but I mean, you know, but if they do establish a new guideline, it should be, because the Agency's determined we need to have this information to make a decision on the continued registration of these products, and if that's not the case, then there shouldn't be a new data requirement.

MR. JONES: Okay, one more question from Melody or comment.

MELODY: I have to plead ignorance on the data call-in process, but I was wondering, this sort of ties into what Julie was talking about. I was wondering if there is another process other than the registration review in which there's some kind of analysis of the data needs that would be open not necessarily just to

within EPA but to the public or for the participation such as what Erik was talking about.

The reason I ask is that a lot of times that my agency has meetings to talk about research needs, so at the end of everything we do, you know, we always think about the future, you know, like what are the research needs. So, I was wondering if you have some kind of process like that in terms of data needs.

And also, since research takes time to do and if there is no data available, then you really do need some lead time before -- you know, to alert people that we need this kind of data and by -- you know, we would need it within this number of years. So, you really have to be thinking about it ahead of time.

MR. JONES: Yeah, actually, there are a number of places that we engage in those issues. When we do identify a data need that we have and have begun to develop the guideline around it, we take that into a public process. That's a

very specific example of engaging the public broadly.

We also engage our Office of Research and Development. Right now, we actually have a -- through the Office of Research and Development some futuristic thinking around data as it relates to chemicals generally, and the NAS is giving us some advice, and that's a very public process as well, and that's not just pesticides. It's chemicals broadly.

We have some -- we are working right now with -- on another group, (inaudible), that's also thinking about the existing framework that we use and are there ways to enhance the power of the tests, and again, that's got a public component to it.

So, a variety of different places that we engage the public on the future of -- the future data needs that can support pesticide licensing.

MELODY: I was wondering, is there a process where the public can bring up their

concerns so that you consider those?

MR. JONES: The three processes that I mentioned all have a public participation part of it, and then we generally -- we also have a system I think that's transparent enough that we regularly do get advice from stakeholders about what they think are specific data requirements that they believe we ought to be focusing on, either in a futuristic way or in a current application of existing data requirements.

Okay, well, I really want to thank Jay and Susan and the PPDC members. I think that you had nearly a dozen members of the PPDC who are very active helping us get to where we are right now, and we couldn't have gotten there without all of you. This has been -- not just the hour and a half we've spent today on this topic, but the year or so that we have spent with all of you trying to move this program forward.

I feel like I am getting close to being properly informed so that I'm able to make

proper judgments around this program. I think there's a little bit more work to do. We talked a little bit about from the first work group some follow-ups. I think from the second presentation that we had, again, I would ask that the registration review work group, if you could take Julie's and Sue and Ray's recommendation and spend some more focused time on it as a work group to see if there are elements of it that there can -- that we can get some consensus around.

I do think it would be particularly interesting in that exercise to sort of play it out the way Ann was talking about, because it would be useful to get advice, not just issue a DCI all at the same time, well, then, what do you advise that we do as it relates to how you then run registration review? So, taking that recommendation and just playing it out through what the registration review program would then do.

But again, I really want to thank those

of you who have really devoted a significant amount of time, energy and effort. I'm feeling quite confident that we are going to have a well-informed rule and registration review program up and running when we finish reregistration. So, with that, we are going to take a 15-minute --

(A brief recess was taken.)

MR. JONES: Before lunch, we have four areas where we're going to be giving you some updates. One of them is -- the last one, alternative non-animal testing, is a follow-up to some PPDC discussion we've had over the past two years, and in our effort to sort of keep you posted on what we've been doing with some of the advice we've gotten, we are going to be talking about that.

The other three are just basically giving you some updates about some important activities ongoing in the Pesticides Program right now. We will start with Bill Jordan, who's going to give us an update on human

testing.

Bill?

MR. JORDAN: Thanks, Jim.

The last time that we got together in May, I told you all a little bit about where we were thinking about going and the important role that the report from the National Academy of Sciences committee is likely to play in our thinking, and the grand outlines of the situation have not changed much since then, but I'll -- for those folks who weren't around in May or don't remember all the fascinating things that I said in May, I'll go back over some of that ground.

In terms of human testing, there are two important reference points or touchstones that we're looking at. The first is the decision by the U.S. Court of Appeals for the District of Columbia Circuit in the lawsuit brought by CropLife America against EPA concerning EPA's press release that said, in effect, we are not going to look at certain

types of human studies pending the development of a final policy.

What the Court of Appeals said is that that press release was a regulation and that it had not been issued or promulgated in accordance with the requirements of the Administrative Procedure Act, and therefore, it was illegal, and they, therefore, ordered us to withdraw that illegal regulation and to proceed as we had in the past, which was to make decisions on a case-by-case basis.

And so, that decision by the U.S. Court of Appeals represents the direction about how EPA is to do its business when it comes to looking at human studies. We are to make such decisions on a case-by-case basis, taking into account statutory requirements, high ethical standards and the provisions of the common rule.

For those not familiar, the common rule is a regulation that governs the conduct of human studies that are either performed by or performed with the support of the Federal

Government, and USEPA has issued these regulations along with 16 other federal agencies, and they basically are designed to assure that there are protections for the participants in any human research. So, the CropLife decision represents one important touchstone.

The other is the National Academy of Sciences report, and the Academy did a job that tackled in a very serious way the questions that EPA posed to the committee, and they gave us some very specific recommendations. We had been looking at those recommendations and recognizing that they cover a lot of different things. In order to think about it, it's not enough simply to announce a policy or to promulgate a regulation.

The Academy actually asked you to deal with a lot of different things, too, and they gave us recommendations in a lot of different areas. They asked us to think about issuing guidance clarifying aspects of the common rule

that are more general in nature, and the guidance would be particular to the types of studies that were at issue.

The Academy made recommendations about reorganizing the review of proposals to conduct human studies for EPA, so it would -- if we adopted the Academy's approach, we would consider reorganization of certain functions within the Agency.

Within EPA, we've been thinking about, looking at and talking about the recommendations of the Academy, and where we are headed is to issue a document that explains a more comprehensive framework for addressing human studies.

As I indicated before, the Academy's report covers a number of different issues, and so our framework will, I hope and expect, address that range of aspects of the Academy's report.

To be sure, as we have said in the past, we need to do rulemaking. The Agency

needs to promulgate a regulation that addresses the questions about under what circumstances will the Agency consider human studies. The Agency -- the Academy made recommendations about extending the common rule and adopting provisions in other federal agencies, FDA's area, for example, about protections for children.

If we are going to do that, we need to do so through rulemaking, and so, we are going to say as part of our framework that we're going to do rulemaking to address and tackle these issues. I won't say today, because I don't think the Agency has worked out these particulars, what that rulemaking will actually say, but it is clear to us that we need to tackle these issues and to use the administrative mechanism of rulemaking.

Now, all of the folks in this room, I am sure, appreciate that rulemaking is a process that is designed to bring a lot of public input, to make sure that matters are thought through

carefully, that they are looked at from a number of different angles, and in order to do that kind of work and to do it well takes time. So, as a practical matter, preparing a proposed regulation, taking public comment and promulgating a final regulation is not likely to happen any time soon.

I've been associated with a number of rulemakings over my career at EPA, and it's years, not months. So, that means that for a good while, for the foreseeable future, we are not going to have a rule that guides how we will operate when it comes to reviewing human studies, and that means, according to the CropLife decision, that we will be operating under our past practice.

Now, that past practice may not be immediately obvious to everybody, so one of the other things that we are thinking about doing is issuing a statement to clarify and describe what the case-by-case approach involves, and we're working, again, to prepare that, make sure that

everybody within the Agency understands that practice and to put that out.

We recognize that the sooner we do that, the better. We are working internally to produce documents. I'm not sure I can predict confidently how long that's going to take, but I think we're talking months, not years. We regard it as very high priority. We understand that not only for the Pesticide Program but for the entire Agency, we're better served by having that in the public domain sooner rather than later. So, I and a number of other folks are devoting a significant amount of time and energy to trying to move that ahead.

I think that that pretty much summarizes where we are on human studies, and I'll take questions.

MR. JONES: Steve?

STEVE: I just have a question. Do you have a cite for the case?

MR. JORDAN: I can get it for you, Steve. I don't have it at my fingertips.

STEVE: Thanks.

MR. JONES: All right, thanks a lot, Bill. Oh, I'm sorry, Erik.

ERIK: Bill, sorry, I had a phone call, and I took it and missed the beginning of your presentation, so I apologize, but did you say what you're doing in the interim with respect to reviewing chemicals and whether you are accepting studies, and if so, what you're using to measure the adequacy of those?

MR. JORDAN: As I -- I started off, Erik, by saying there are two touchstones, one of which is the CropLife decision, and that direct EPA to proceed on a case-by-case basis and to reference statutory requirements, high ethical standards and the common rule, and there's been one case that I'll mention or one situation where we have done some work in this area. It's not in the pesticide area.

The Acute Exposure Guidelines Program develops regulations for emergency responders about what levels of acute exposure represent a

hazard, and as part of that, they review the scientific literature and attempt to make sense of it in terms of recommending a particular level.

Some of the data available from the public literature include human studies, and we've issued a notice in the Federal Register, and I'll let that speak for itself, summarizing the available human studies database for that consideration and how we went through thinking about the ethics issues in connection with that as well as the science issues.

ERIK: If I could follow up on that, I did take a look at that, and one question I have is there were several NAS recommendations or NRC recommendations for creation of a series of new processes within the Agency and outside review boards, et cetera.

Are you basically starting to accept those studies as you did in the AEGL, I guess it's pronounced, situation without having created all those review boards and followed the

recommendations of the Academy?

MR. JORDAN: The AEGL -- that's the acronym, Acute Exposure Guideline Level or Limit, I'm not sure, pronounced "eagle" -- didn't go through any external review before we sent it to the National Academy of Sciences, which is itself an external review. The NAS in the AEGLs program does play a very prominent rule, and as mentioned, this is a case-by-case kind of approach, and so I don't think it would be necessarily appropriate to conclude that what we've done on the AEGLs program this time around is -- locks EPA into a particular position about using external peer review or not.

MR. JONES: Shawny?

SHAWNY: I'm just -- I'm wondering, it's a little unclear, have cases been submitted that the Agency has reviewed on a case-by-case basis on pesticides involving human testing?

MR. JORDAN: We have a number of studies and a number of pesticides under review. We haven't made any final decisions for the

types of study -- for pesticides for which the types of studies that were the focus of the controversy, intentional dosing studies to identify or quantity tie toxic, systemic end point. We haven't made any decisions on those, but we do have -- it's no secret -- lots -- lots -- well, we can argue about what's lots, but we have more than a dozen pesticides for which that kind of study is available and which people want EPA to consider and which other people want EPA not to consider.

MR. JONES: Pat?

PAT: Just to build on that, I guess the one thing that I would urge you to think about as you issue this statement of clarification is trying to distinguish between those studies of concern, the intentional third-party dosing, and those studies which ought to be accepted I think not on a case-by-case basis but as a matter of what I guess I would call an interim policy, which would be the human clinical patch studies that

you've always accepted for purposes of registration in the past.

I think, even recognizing, you know, sort of how loaded these issues are, I don't think NAS has found that to be the focus of concern, and I don't think that you should either, and I think there would be some real benefit going forward to having a policy at least an those that's not case by case.

MR. JONES: Okay, thanks, Bill. Oh, sorry, Erik, you're back up?

ERIK: Yeah, sorry. I never put it down, sorry.

MR. JONES: Go ahead.

ERIK: I guess the Agency has less than two years before you have to wrap up all the FQPA reviews, and I'm presuming that there won't be new regulations out before then?

MR. JORDAN: You can make more money betting against regulations coming out in -- that fast.

ERIK: So, you know, I understand

you're saying there will be a case-by-case review, and I guess aside from what the CropLife court said, which was -- well, everybody can read what it says -- is there any degree of clarity that you can offer as to how the Agency interprets that or where we go from there?

MR. JORDAN: I'm hoping that the clarifying statement will, in fact, clarify things, although --

(Laughter.)

UNIDENTIFIED MALE: That's clear.

MR. JORDAN: Yeah, but I'm going to say that this -- that my remarks this morning are not an intent to try to clarify that. I don't think I want to try to speak anything more than to point at the CropLife decision and to say that as quickly as we can move along and get things together, we will try to get that clarifying statement out, and Erik, you and others can be the judge of whether or not it serves any -- has any value in clarifying matters.

MR. JONES: Let me just add that although the Agency reserves its right to reverse me on what I'm about to say, I reserve the right to reverse myself as of right now, the plan is that we will not rely on any study of a regulatory decision before the clarifying statement is out. I think we think it's a better approach, is to let people to know what our operating approach is going to be before we rely on it, so people have somewhat notice about how we're planning on doing that instead of issuing a regulatory decision and letting people sort of figure it out because of their wiles or they've followed the web site.

So, as of right now -- and again, you know, that could be changed by someone else above me in the Agency or by my consideration -- unlikely that would happen, the latter would happen -- but as of right now, the plan is to have a clarifying statement out as to what our interim approach is going to be during the rulemaking process before we issue a regulatory

decision that relies on such a study.

Thanks, Bill, and I hope I don't live to regret those words.

MR. JORDAN: I don't plan on it.

MR. JONES: Okay, so Rich Dumas, from the Special Review and Reregistration Division, is going to give us an update on a provision of FQPA which many may have overlooked, but it's worth reporting on the progress that we have made on that.

MR. DUMAS: Okay, as Jim mentioned, in FQPA, there's a provision that for tolerances -- thank you -- that for tolerances that were based on anticipated -- the use of anticipated residue data, that we review and acquire data periodically.

More specifically -- second slide -- FQPA requires that we acquire anticipated residue data for tolerance decisions that are based or -- are based on anticipated residue data five years after the decision is made.

Separate from that, actually the

very -- in your handout, right after that, the provision deals with percent crop treated. Percent crop treated, although a very important part of risk assessment, is treated separately. It is -- it calls for a periodic review of the percent crop -- the percent crop data -- treated data used.

Okay, so, once again, under FQPA, anticipated residue refers to the level of residues on the food. So, how much residue you'll find on that piece of fruit. That's really what we're talking about.

OPP uses both the anticipated residue level and the frequency in food or the frequency that the chemical is used on food in doing its dietary risk assessments or its -- and its exposure assessments. The way we look at frequency typically is we use the percent crop treated. So, that's sort of the linkage between the two.

And today is to focus primarily on that anticipated residue requirement and talk about

how we're planning to address that, how we have been addressing that, actually.

The two major components in anticipated residue or types of anticipated residue data that we come across on a regular basis or use on a regular basis are field trial data and monitoring data, and I want to take a few minutes -- I know for most of -- many of you, this is OPP 101, and you probably don't need it, but just to make sure we're all on the same page, let me take a few minutes to just talk about each of those types of data.

Field trial studies are designed to get the -- come up with the maximum possible residue from the current legal use; that is, it's based on the maximum rates, the maximum frequency of applications, the shortest interval between applications, harvest occurring right at the PHI. So, basically if we do not have a situation where the labeling has changed, that field trial study holds and represents -- adequately represents the maximum level of

anticipated residues that we would expect to find.

Monitoring data, on the other hand, is based on what's happening today, on the actual use application rates that are in play today, how frequently the pesticide is used. If there's three applications on the label, growers may only be using one. The -- most crops are not actually harvested right at the PHI. Maybe that's when the first day of harvesting occurs, but there's certainly harvesting that would occur after that. So, the -- we would expect, or in reality, we end out seeing residue levels that are lower than the field trial when we use monitoring data, and those things can change.

We can have changes in pest pressure. We can have changes in the --

(End tape 2-B.)

MR. DUMAS: -- and therefore change the actual residue levels today.

Once again, the next slide actually I just want to mention, that once again, this is

what the wording of FQPA has. It's a quote. You have the exact one, but once again, it's the concept that we will revisit anticipated residue decision -- tolerance decisions based on anticipated residue on a five-year schedule.

And then there's the second provision, which -- and also, this is a one-time revisit. It's five years after the tolerance decision, one time. Percent crop treated is that we -- calls for us to periodically look at the percent crop treated that was used in our tolerance decision, and that's an ongoing process.

Now, how have we chosen to interpret the provision? We're reviewing right now or we have been anticipated residue decisions, and we're trying to determine -- and what we've been I think fairly successful in determining -- which ones of those -- which of those decisions are likely to result or have data or new data could be made available that would, in fact, change the anticipated residue that we used in our original tolerance decision.

So, we were looking for a focused way of narrowing down the field to figure out where we really needed to do additional work, and that's -- so, that's where -- that's what we've been doing so far.

I think I actually sort of jumped ahead of myself a little. Let me -- go one more slide, please.

What we've been seeking is to find the most efficient way to determine which anticipated residues may increase, and thus, may need new data, and efficiency for our purpose is -- not only deals with getting the data we need. It deals with acquiring it in the most efficient way, the most expeditious way possible, and that makes sense for us for resources. It also makes sense for the regulated community. If there's data we don't need, we shouldn't be requiring it.

So, the way we would approach this is we developed a tiered approach and to really focus in and deal with the chemicals where there

may have been changes. The tiered approach started off where we looked at -- we started with a universe of chemicals, many of which, it will turn out when I get to the next slide, were ones that really did not use anticipated residue data. We decided to start with a universe and err on the side of looking at any chemicals that could conceivably have had an anticipated residue data used in the decision.

Let's see, then we went through each of those cases and looked at which ones actually did use anticipated residue. From there, we looked for the ones that did have anticipated residues that might change, and from there, we actually focused in on those individual chemicals for a more in-depth review, to identify tolerance by tolerance which data might need updating, and the next step would be how would we best acquire that data.

So, to summarize what that tiered process has given us, we started off with 99 chemicals, AIs, and they were ones that were

registered or there was an action, I should say, and action would either be a reregistration decision or a major registration decision, and it would be between August of '96, when FQPA was passed, to the end of 2000. That was the first screen. Basically we're in a catch-up mode to be quite candid about it.

Of those 99, we found that 41 of those chemicals, for at least one tolerance, there was some anticipated residue data. Of those, 37 were field trial data, no monitoring at all. And once again, if we -- if it was just field trial, our basic view is as long as there was no major change in that registration, we would -- that field trial data would represent the maximum anticipated residue.

Of the seven other chemicals, there was some monitoring data for one or all uses. I don't think there was any that were all, but some of them were extensive use of monitoring, some of them not so extensive. Of those seven, it turned out that there were three that have

had updated risk assessments just in the last year or so with new monitoring data typically from PDP, if not exclusively PDP data.

So, what that leaves us with are four chemicals that we -- out of that body of 99 that we really have to dig into in more depth, and we're in the process of doing that, to go tolerance by tolerance and making a determination of what data would we need to continue the safety finding, find -- correct the safety finding, whatever it might take, and that's really where we stand on those four right now.

Overall, our next steps are acquiring the data or the information that we need in reviewing the four. We are still in the process of developing our internal process to make sure -- so, we do the 2001 onward chemicals in a more systematic way, and we're still working out the bugs of what that process might look like. We have a rough idea, but we are still working on that. And to stress that even though we're

not looking at percent crop treated right now, we fully recognize the importance in that and risk assessment, and we're looking for ways -- we're still working on ways to -- how would we implement that provision in FQPA? Then the last thing is we're looking for your guidance on how would we formally roll out this process?

And the last slide is just the handouts that you should have.

MR. JONES: All right, as Rich said, one of the things that we're most interested in hearing about, although I can understand that given the newness of this issue, I'm sure that many of you may have questions, which is fine, but what we're most looking for around this is how -- what kind of advice do you have about how we ought to basically show our work? Are you thinking of, you know, putting this into an e-docket and making it just generally available, the analysis that surrounds it, some kind of a notice? How does the PPDC think that the Agency ought to make it more publicly accessible, the

work that's gone into and the choices that we've made?

Let me just open it up now for just general questions or otherwise.

Erik?

ERIK: I'll try to answer your question, Jim, as well. I had a question about the monitoring data. How do you -- how are you able to verify that the data you get from the monitoring is actually representative of the use in that industry versus representative of some -- you know, perhaps conscientious growers that are willing to work with the Agency or the chemical producer to do the monitoring?

And along those lines, I would find it helpful, an e-docket, to post as much of this to allow us to review it to, you know, get a handle on is this representative from our experience.

MR. DUMAS: I mean, monitoring data, I may need some help from Al on this, but most of the monitoring data that we use is based on PDP, which is a fairly statistically robust data set

and process. In the cases where we might have used market basket surveys, usually our statisticians work pretty close with the people conducting the studies to make sure those -- the site selection, where we -- grocery stores, wherever we choose are a statistically robust selection. So, that's pretty much -- we're fairly confident in PDP over time. It's a growing and improving system, and I think that's probably all I need to say.

MR. JONES: Yeah, that's the answer. (Inaudible.)

UNIDENTIFIED MALE: I guess I can just add that PDP is pretty much designed to capture the American diet. Sampling is (inaudible) some 700 to 800 samples are typically taken once a commodity's in the program, taken from distribution centers. That's the closest we can get to the consumers, not the supermarket, but the step just before that. And again, the statistics of the program are available I think on the web site, but we do believe it to be

representative.

MR. DUMAS: By the way, does everyone know that PDP stands for Pesticide Data Program, which is a USDA program? I think I never actually said that.

MR. JONES: Thanks.

Shawny?

SHAWNY: First, I would definitely agree with the e-docket format. I am -- for our group, we have found the e-docket to be extremely useful, especially because it lists not only agency documents but other comments as well. We just find it very, very useful.

Also, I do have a couple of questions. Just for the field trial data that you collect, it says changes in use practices cannot change residue levels. When you say "use practices," it's not uses.

MR. JORDAN: The -- no, the --

SHAWNY: Use practices.

MR. JORDAN: -- the concept is use practices that a -- that the maximum rate on the

label is four pounds, growers may be using two pounds --

SHAWNY: Okay.

MR. DUMAS: -- but over time, they might use three pounds because of pest pressure.

SHAWNY: Okay, perfect.

And one other question is when you looked at the -- you have seven cases here that you used the monitoring data, and three have recent assessment with updated data. Of those three, were there new anticipated residues found in the assessments or new residue levels other than --

MR. DUMAS: The actual levels, I can't say, but what I can say is that there was a registration decision and an FQPA finding made for those -- for those tolerances, yes.

SHAWNY: So -- well --

MR. DUMAS: It's a (inaudible) safety finding.

SHAWNY: I'm just wondering what kind of information should we gather from the three,

or is there any kind of I guess generalization that we can make about the ARs that are going through? Do they seem to be consistent with the -- after assessment? Does that make sense?

MR. JONES: We could certainly look at that. I think from my perspective the most important thing is that it was safe four years ago, it's safe now.

SHAWNY: Right.

MR. JONES: We would have had I think some anxiety had it gone from safe with earlier ARs and new ARs led to a different conclusion.

SHAWNY: Okay.

MR. JONES: But you got the same conclusion both times.

MR. DUMAS: Exactly.

SHAWNY: Yeah, that's what I was looking for, thank you.

MR. JONES: Okay, Erik and then Shelley.

ERIK: What date are you counting from? Have you thought that through? Are you

counting, say, from an IRED date or are you counting from a RED data or what's the plan?

MR. DUMAS: Good question. The -- for the ones that we looked at, we either used significant registration action or the RED. If it's an IRED, we haven't made a final tolerance finding, so that wouldn't be a part of these.

And then the one thing we did do is let's say there was a RED in 1997, and there were some new uses in 2002. We would look at that whole body of data for that chemical. So, in -- so, actually, for these 99 chemicals, probably look through a minimum of 300 residue chemistry chapters, risk assessments and so on. So, we did look at the full body, but we start -- we set the clock on the oldest, be it registration or reregistration.

ERIK: And just two other quick questions. Are you -- PDP, as I understand it, does not include farmers' market and you-pick farms. Is that correct?

MR. DUMAS: Correct.

ERIK: What's the Agency's plan with respect to considering that since there are millions of people that eat that way?

MR. DUMAS: Well, that's a good question. I mean, that -- basically, what we're looking at is how we would routinely do our risk assessments today, and --

MR. JONES: Yeah, I don't believe we have plans to collect that information, but maybe tomorrow I can give you some -- we may have some analysis going on around that, that if we do it, I will let you know, but right now, we don't have any plans to go out and collect or ask USDA to collect that data, residue data, from a you-pick or a farm.

ERIK: I will just say there is anecdotal data suggesting that the residue levels are often quite a bit higher in that situation, especially for you-pick, and I believe that the Agency actually considered that data for a couple of chemicals, and you know, it's something that we think is important to

consider.

My last question is, what are the four pesticides?

MR. DUMAS: You know, I don't have them with me. I know they were ones from I believe -- I could -- I can certainly find them and identify those. I just don't know them off the top of my head.

ERIK: Yeah, just send an email around to everybody maybe.

MR. DUMAS: Yeah.

MR. JONES: Shelley?

SHELLEY: I just wanted to know how much of the monitoring data, what was registrant data, because I thought from our earlier discussions on FQPA that sometimes monitoring data was registrants, and is all the field trial registrant data?

MR. DUMAS: Field trial, yes. Monitoring, for the individual chemicals, if I recall, it was either FDA monitoring or PDP. I don't think -- there may have been a market

basket in one of them. I honestly don't remember. That would have been a registrant-generated if it was a market basket study.

SHELLEY: Because I have this recollection that some of it, like applesauce or various cases like that, were done by the registrant, but would that have been in the field trial kind of thing?

MR. DUMAS: You mean some of the processing studies or --

SHELLEY: Yeah.

MR. DUMAS: Those would have been guideline registrant studies.

SHELLEY: So, is that considered field trial data or monitoring data?

MR. DUMAS: It's another item that would be adjusting our -- clearly these are the two most significant contributors to anticipated residue. That would be another factor that would go into a risk assessment in making a tolerance decision, yes.

MR. JONES: It would be neither, though. You would take residue data from either monitoring or field trial and apply processing factors to generate --

SHELLEY: Oh, I see.

MR. JONES: -- to figure out what the various food forms, what their residues would be.

Julie, is your card trying to stand up?

MS. SPAGNOLI: Yes, it doesn't want to, and I guess I was just trying to get some clarification now. When a tolerance decision -- so, this could be the issuance of the first tolerance for a chemical --

MR. DUMAS: Yes.

MS. SPAGNOLI: -- and so those would obviously be field trial data. So, the date then would be five years after that initial tolerance was established, and so if four years after the initial tolerance is established new tolerances are issued for some new uses, how does that affect that clock? You still have to

look at it five years after that initial one, and that can be the one you can sort of -- almost the easy off ramp, again, because it was just done? If it was done as part of the -- establishing the --

MR. DUMAS: I mean, depending on the actual timing, I think we haven't totally worked out how we couple them. I think we've been going -- taking the approach that if it was anywhere in that first group that we looked at, we would -- we were looking for any more recent assessments, and like the four that I mentioned or the three that I mentioned were ones where there was a new use or some registration action that made us go back and re-assess the entire risk assessment. So, it was an original group. I think at this point we're saying that one is settled for the anticipated residue portion as of today, and that 2003 date would restart the clock -- well, actually for that one tolerance.

MS. SPAGNOLI: Because it's really by tolerance by tolerance, not by chemical, right?

MR. DUMAS: Right.

MR. JONES: By tolerance, yeah.

MS. SPAGNOLI: So, you could have -- you know, if a chemical has had a lot of -- you know, every year had a new tolerance added, do you still have to go back five years after each tolerance and just at least --

MR. JONES: We confirm -- I believe the clock restarts.

MS. SPAGNOLI: Restarts each time.

MR. JONES: Each time you do it, because you validate that your data supports the action.

MS. SPAGNOLI: Okay. I mean, that makes sense. I just...

MR. JONES: Okay, I realize that was kind of a deep topic to get into in an update. My mistake there. It was a good topic. I just think it was a short amount of time, and I recognize that.

The next topic, which is also going to do, is activity-based REIs, let you know where

we are on an issue that we have been working with a number of you and a number of other stakeholders for some time now.

MR. DUMAS: Interestingly, the last one, many of you never -- probably never focused on. This one, many of the people in this room have been actively involved over the last several years with this issue.

The issue of activity-based re-entry restrictions has been something that is -- really continues to be misunderstood, and I will take a little bit of time to just work on some definitions here, but the real issue for today's is to give you an update on the -- how we might label when we're looking at activity-based re-entry and some of the processes that we've gone through in the last several years.

So, let me just start off with what is an activity-based -- what is activity-based re-entry? Basically it deals with one re-entry duration for some set of activities and another for some other set of worker activities in the

same crop. So, one duration for harvesting and another duration on a label for hoeing, for example.

And there are essentially two ways that we've identified for potentially dealing with how do you label such a risk management decision. One would be the use of what has become -- is being called multiple REIs, which is actually a confusing term because it has a totally different meaning somewhere else in registration, and what I would call an REI with an exception or a prohibition.

Let me just go through each of those real quickly. A multiple REI would have an REI for one group of activities and another REI for another group of activities on the same chemical, the same crop at the same time, so the same field.

So, for example, what it would look like would be the REI for harvesting and pruning is 14 days, and the REI for hoeing is two days. So, that would be pretty much how it would look

like on a -- you would find it under the directions for use on a label. That's how it has appeared on the few occasions that we actually did that.

The alternative would be same basic risk management conclusion, except we had set the REI itself on the longest duration, whichever activity goes with the longest duration, and then use an exception for that other activity or set of activities. So, it would be REI's 14 days, same example as before. Exception, workers may enter the treated area 48 hours after application to hoe. So, that would be the alternate way to do this.

And I just can mention that somewhere in your package, there's two examples, real world, real cases that were kind of out of order, because I'm -- the example one would be the multiple REI. It comes from a real label. The example two would be an REI with an exception, also a real label.

So, there's some comparison -- some

points about the two approaches. Both of them would achieve the same risk management goal. Multiple REIs tend to create some inconsistencies with the worker protection standard, because that was designed around the REI. That's why we brought Kevin Keaney here, so if there's real specific questions on that, he can address that. And regardless of which one we use, good communications and outreach is critical.

Now, just as an aside, another worker protection point is independent of this discussion, there -- under WPS, there's a set of exceptions and exemptions. Those tend to cover a broad category of chemicals, a certain tox category group of chemicals, and I have them listed here. I am not going to be discussing them. There's also a handout that gives you the basic provisions for each of these exemptions, but they're WPS exemptions and exceptions. What we're talking about today are individual product AI type decisions that would go on a label.

Now, in the discussions over time, there are some pros and cons to either approach. Some concerns that have been raised with either approach is that they both have a tendency to compromise the effectiveness of the worker protection training that has gone on for the last decade. That is, do not enter a field during the REI. So, that concern has certainly been raised by a number of people.

The more complex we make a label, the lower compliance. That's pretty much true of any sort of -- the more complex, the less voluntary compliance, and it becomes that much more difficult for the states to actually enforce the label.

There are some advantages to the approach. It affords the risk managers -- it affords the flexibility to help and maintain a critical use for the grower community. It does a little bit -- does a little bit better job of having a label reflect our understanding of risk. And it does provide the risk manager with

an additional risk management tool. So, there are some pros and cons to it.

Now, in the late 1990s, we -- there was a few chemicals where we actually used the multiple REI, as I defined it earlier, and very shortly after that decision -- after we made some of those decisions, there's tremendous push-back coming from our own worker protection staff, from those responsible for enforcing both state and regional, and the grower community who just didn't know how to interpret it, what to post. So, there was quite a bit of confusion and with the true -- with the multiple REI as I defined it.

So, what we did shortly after some of those decisions is formed a -- basically a regulatory work group with the purpose of coming up with a way to, if possible, have similar risk management decisions, but might be more effective, enforceable and people can live with them better, essentially. And that process involved the headquarters staff, EPA field and

headquarter enforcement, risk managers throughout OPP, from registration and reregistration, and our worker protection staff.

Now, what that effort culminated into was the guidance that is also in your package that's dated September 6th, 2001. Now, what that guidance -- that guidance was designed for our product managers in registration, the chemical review managers in reregistration, and to the extent it was applicable to the other two divisions, their chemical review managers, also.

And what that guidance said is that essentially we'd use the exception/prohibition type approach; that is, we'd set a single REI, and when there is a well-defined agronomic need, we would consider an exception in those cases.

Just an aside for a second, I keep talking about exceptions. There is this notion of a prohibition. If that one outliar activity tends to be way out in time, like 30 days where everything else just seems fine in our risk assessment at two days, we may consider the

possibility of a 48-hour REI with a prohibition on that one activity for a month. So, that is what's referred to when I say "exception/prohibition" throughout this document, but exception is more likely to occur.

So, the other part of that guidance was we would do that two-tier, that is, REI with exception, and the push-back we certainly got from our co-regulators was use it sparingly for some of the reasons we talked about earlier. It was really meant to be -- the guidance was really meant to be internal guidance that we shared pretty liberally with anyone who asked for it.

Subsequent to -- within about a month or so after the guidance was complete, there was a lot of questions. Well, what level of information do we have to provide to demonstrate that the exception -- there's really a need for the exception? What we relied on was we pretty much went to the WPS exception language and sort of built our framework for here's what we

ideally would like to see. In practice, what we really ended up doing with those who were interested in the exception, we would try to in a more collaborative way sit down and say, here's what our real concern is with this chemical or this activity, and that would be an opportunity to explain what the agronomic need was and understand their concerns better. And that's pretty much how the process was working, and it was pretty much very much a case-by-case. There weren't that many of them, but that's pretty much how we started with it.

About a year after, there was starting to be more and more interest for a variety of reasons, and we started a broader stakeholder -- to get broader stakeholder input. We had three large stakeholder meetings, the most recent was this past August, with -- that had representatives -- we tried to make sure that we had representatives from grower groups, worker advocacy groups, the registrants and USDA and others. So, we had -- and certainly our

internal stakeholders. So, we had a pretty -- have a pretty good idea over time what the nature of the issues have been and what the stakeholders' perspectives are.

States and EPA enforcement people are certainly concerned with the enforceability. The registrant community, who has generated quite a bit of exposure data, would like us to more routinely use their data in making -- in our labeling decisions. Worker advocacy groups were certainly concerned with the possibility that the exceptions may, in fact, weaken worker protection, and we would to, if we are going to do it, consider offsetting safeguards.

(End tape 3-A.)

MR. DUMAS: -- groups were interested in was preserving a use and maintain as much flexibility as possible. I'm sure I'm oversimplifying everyone's point of view, but those are the really take-home messages that I've gotten over time from everyone.

We have had some really interesting

suggestions coming out of these, and the idea of -- ranging from more routine use to exceptions and prohibitions; removal of the unforeseen language on some of the WPS exceptions, particularly the irrigation and low contact; making products with exception, double notification chemicals, so they would be required to have posting; expand what goes on postings is an idea; incorporate the WPS exceptions more routinely on our labels. So, there's a range of interesting ideas that have come up, and quite frankly, a lot of these might address some of the REI questions, but they may have ramifications that we really need to better understand.

So, where are we on this? I think our plan right now is to continue our case-by-case, and then we've got quite a bit of input over time. I think we have a pretty robust understanding of all stakeholders' points of view. We want to go back and sort of digest all the ideas that we've gotten over time. I've

mentioned a few. I've got a shopping list of 20-something ideas that we might want to consider. So, we want to go back and internally consider these.

What we can say, that before we would consider making any permanent change to our case-by-case, is we would have some basic guiding principles. We would not change our current case-by-case, and we would want it to provide equal or better worker protection. We would want to maintain enforceability. We would want it to be manageable for the growers. We would want it to be understandable for whoever -- all stakeholders, and we would be seeking broad public input on whatever change may be considered in the future.

And then the last handout is simply all the items that you have in your package.

Any questions?

MR. JONES: Let me just say that this is truly an update in the classical sense of the term "update." We -- this isn't the opportunity

for further dialogue, discussion. We have provided a host of opportunities, of which many, if not most of you, have participated in. I really did want to -- feel after the meeting in August, we had a responsibility to get back to our stakeholder community, and certainly this isn't the only way we'll do that, and let you know where we are.

Obviously we have not been, despite several years of working together with many of you and others, been able to come to a consensus. So, we are, as of right now, sticking to the plan that Rich had identified, case-by-case approach with documentation supporting any agronomic need. As Rich had said, we have not gotten many of these. I don't expect that we will get very many in the future. So, I really don't want to get into much more dialogue on an issue that's been -- had a lot of dialogue.

That being said, we will certainly entertain some questions or further advice.

Erik? But not much.

ERIK: I'll be really brief. I think this is a profoundly bad idea. The difference between a multiple REI and REI with exceptions I think is a linguistic that I think will be only relevant here in D.C. and completely lost on the farm worker community. I think anything that's going to require more training, and as I'm sure we're going to hear this afternoon, the money for training's been cut back. So, I don't think it passes the test of -- I have no idea how farm workers are going to have any idea of how to comply with this.

And I think your slides 7 and 8 really summarize the issue. The benefits are increasing use. The REI is supposed to protect farm workers. By doing this, you're jeopardizing farm worker health; you're not further protecting it. I think the decision is very clear.

And finally, what I would encourage the Agency to do as part of its review, if it has

not done already, is to look at to what degree are the state lead agencies and your regional EPA offices actually enforcing currently REIs. My experience is that they are not, and if they are not -- and second, to what degree are they finding violations if they are, but if they're not, I don't see how the Agency can move forward on this without making sure the existing REIs are actually being enforced, because then it's another theoretical regulation that when it comes back to the farm worker community, we're going to pay the cost.

MR. JONES: Thanks, Erik.

Shawny?

SHAWNY: I'm just wondering what the process is at this point. Now that we're at the recommendation, is there still -- is there public comment? Is there -- I mean, I notice that in some of the public comments that I've seen, I don't think the unforeseen issue was addressed.

MR. JONES: The -- there's been a lot

of opportunity for public involvement in the evolution of this, as articulated. I think it I point we do need to capture it in writing and make people aware that through, you know, means other than oral presentations like this and sort of put it down in writing. Whether we use some kind of an FR notice or otherwise, that hasn't been determined. We clearly need to do that, though.

SHAWNY: So, you're saying it probably will be opened up one more time for a dis -- for -- like through an FR notice?

MR. JONES: Well, again, I'm not sure we're going to take further public comment on it. We may well do that. That choice hasn't been made. I feel -- we feel that we have provided ample opportunity for public involvement, and we also feel that we have heard from all of the stakeholders, that their perspectives have been heard, but if it's the advice of others that we haven't, it would be useful to know.

Erik, for example, I think his comments have been fully understood by the Agency. What he said today is I think what we understood him to be saying to us earlier. But if there are people who think that we really do need to do one more round of comment, that's something we would take under consideration.

SHAWNY: Okay.

MR. JONES: Erik?

ERIK: Yeah, I'm not going to comment at length. I just want to say, we also find this a troubling approach, and I guess my one question is, has the Agency -- similar to what Erik's question was, but do you -- have you guys collected data, sort of random field data, on compliance currently with REIs, where there's unannounced inspections and you look at whether people are complying now?

And if not, it would seem like adding another layer of complexity might be an advisable -- you know, it -- it's really important to have an idea of what the realities

are out there now before introducing even more complexity to -- anecdotally, at least from what we've heard, there already are very significant problems with cut-backs at the state level in inspections and enforcement to really make this happen.

So, I'm just wondering if you have any of that kind of data or plans to do that kind of random, unannounced, sort of statistically sound sample to determine whether currently REIs are being complied with.

MR. JONES: I'll have to touch base with OECA. I'm not aware of it, but OECA or state lead agencies may have the ability to provide that. We'll check on that.

Shelley and then Lori.

SHELLEY: I just want to echo Erik's sentiments that the problem from the worker perspective is that neither your multiple REI nor your REI with exception or prohibition approach is consistent with the worker protection standard or the training that people

will receive, and this is really an area where there is a gigantic disconnect between folks here in Washington and folks on the ground, and keeping in mind that what workers actually get under the worker protection standard is 15 minutes of training once every five years.

This degree of complexity just does not fit in that any use of this, on a case-by-case basis or a policy basis, should not go forward unless it's consistent with the worker protection standard, and in our view, was certainly echoed by the states, who have the burden of enforcing this, when they found this as troubling as we did, and you know, before you issue another registration with either of these approaches, you know, we'd like you to go back and look at the worker protection standard and make sure that anything that you're contemplating really is consistent with that and that you amplify the requirements of protection in the worker protection standard before you create more complexity on the re-entry interval.

MR. JONES: Thanks. Lori?

LORI: I just wanted to comment from the growers' standpoint, it is in the best interests to protect the growers, and there are -- and I come from California -- there are random inspections that do occur, and there are penalties that can and are assigned to people that are not complying.

When applications or activities are done, it is incumbent upon the grower to advise his workers. So, it's -- the training and the notification is happening more than just a 15-minute training period over five years.

So, from the growers' standpoint, it is something that we're very concerned about. We really do, especially in the high-intensity crops that require a lot of labor and so forth, we really do need to maintain as much flexibility in the use patterns of these products.

MR. JONES: The other Laurie.

LAURIE: I would just like to say I

agree with some of the things that Shelley and Erik have said, especially from the tribal standpoint of trying to deal with worker protection issues, and the other thing is is that I might not be aware of it -- of where this was presented at all of the other forums, but I know that we haven't discussed this at the Tribal Pesticide Program Council. So, maybe another review of this might be needed.

MR. JONES: Thanks, Laurie, appreciate that.

Okay, well, we are going to break for lunch now. We will start after lunch with the final update from Tina Levine.

Needless to say, sometimes we are unable to achieve consensus through this and other processes that we use, and I think we just all need to recognize that that is going to happen sometime with some of the issues that we are dealing with. Otherwise, I think we've -- that being said, I should say, I think we've had a pretty productive session this morning, and we

are going to take an hour and 15 minutes since there's -- you may need to walk five or so minutes to get to lunch, I think we need to provide for an extra 15 minutes. So, if we could all be back here ready to go at 1:30, I would greatly appreciate it. Thank you.

(Whereupon, a lunch recess was taken.)

AFTERNOON SESSION

MR. JONES: We have 15 minutes we need to make up, maybe a little bit more than that, because we are one topic behind, too.

Okay, I think as most of you I assume remember, over the last four or so PPDCs, we have had a number of somewhat in-depth discussions around alternative testing, and we have committed to keep the PPDC apprised of our endeavors as a number of members of the PPDC have been engaged with the Pesticides Program in pursuing a plan of work around this.

So, this afternoon, Tina Levine, who's the acting director of the our Biological Economic Analysis Division, is going to update the committee on where we are as it relates to our -- the progress that we've made over the last year or so. Thanks.

MS. LEVINE: Thank you. I didn't notice until this morning that I had been given the slot, the dreaded shot, just before lunch, so I was kind of happy to find that I had been

moved to just after lunch, although it may be a toss-up, because before lunch, people are anxious to get to lunch, and after lunch, you know, they start to feel a little dozey. So, I'm going to try to make this as brief and hopefully keep you awake for the next few minutes.

You remember that back in May, I guess, Debbie Edwards gave you an update on where we were with the alternative non-animal testing project that the PPDC has been involved in, and the goal of this project is to develop a non-animal assessment approach for evaluating the skin and eye irritation potential and labeling requirements for anti-microbial cleaning product formulations. So, it has a fairly narrow scope.

We had a number of different stakeholder participation in this project. We had PPDC members, Troy Sydel from PETA, and Len Sauers from P&G, and Pat Quinn from the Accord Group, many EPA staff and some managers have

also been involved from almost every division in the program. We have participation from the Institute for In Vitro Sciences, and S. C. Johnson has also been involved.

The plan had been to hold a workshop to evaluate the alternative methods for eye and skin irritation, and this was presented at the last PPDC meeting when Debbie gave you the update.

In June, Jim Jones sent a letter to Bill Stokes at the inter-agency coordinating committee on the validation of alternative methods, which is the ICCVAM, outlining our plans for the workshop and requesting that the ICCVAM participate, and when Bill Stokes got the letter, he started thinking about the ICCVAM participation, and he invited Jack Housenger and myself to the August ICCVAM meeting, where they considered the request.

They suggested that instead of the work plan that we had outlined, that the ICCVAM convene an independent scientific expert panel,

which would have the opportunity for public input. That's basically the way the ICCVAM works these test method validation projects. And they proposed an alternative work plan. Next slide.

In this work plan, the data collection and preparation of the background materials would take place during the summer and the fall of 2004, which pretty much tracked what we were planning in terms of preparation for the workshop, and instead of having a workshop in early January or sometime in January or February, that would be when the background materials would be presented to the ICCVAM.

But they proposed that there be a presentation to the combined meeting of the ICCVAM Ocular and Toxicity and Dermal Corrosivity and Irritation Working Group on October 12th, and that meeting did occur, and I'll tell you about that in a little bit.

Then, they proposed that the ICCVAM -- that these -- that the recommendations from the

ICCVAM go to the PPDC, which is what's happening today, and they are also presenting it to their Scientific Advisory Council.

What will happen is that the ICCVAM will put out a public call for nominations of experts for the review panel and for any relevant data and/or experience for the proposed test methods and hazard assessment strategies, and that will happen about 30 days after we sort of trigger it. They'll start putting out this call.

There's also a possibility that this panel, the independent panel, could be a joint SAP exam panel. We could propose people on the panel that would make it sort of a joint panel. So, that might eliminate a review step if we did that.

So, as I said, and basically what they were saying is that they expected in January that a background review document would be submitted to them. It's going to turn out that that's going to slip about three months. So,

most of the dates that I've put in for the current work plan take into account that. It's probably not going to be until around March that a background document could be prepared. It takes them about six months after they receive the background document to convene the panel.

Then, that would mean that their report would be released for public comment then sometime in the fall of 2005, and if necessary, they could then present their report and any public comments and proposed recommendations to a FIFRA SAP panel in the winter, but that might not be necessary if it was a joint panel. And the final recommendations would be forwarded to the federal agencies for their implementation in late winter 2005.

So, in keeping with this schedule, we did meet with the ICCVAM Ocular and Dermal Working Groups, Len Sauers and I presented an overview of the purpose of the project, and then Roger Curran and John Harbell presented the scientific basis of the project, and that

happened on October 12th, and the reception was very good. I think the ICCVAM did understand the limited scope of what we were trying to do, and they were quite interested in pursuing our proposal and working with us to see this through to completion.

With that, I open it up to questions.

MR. JONES: I think that the issue for the PPDC on this topic, other than questions you may have for Tina, is that the last time we got together, we asked you if the proposal -- the work plan we had was -- you were all comfortable with, and to be completely transparent around this, we now have an alternative proposal, which our judgment is very consistent with the proposal that we were following, and it's been modified because one of the key players in this ICCVAM has some ideas about how they see us going forward, but again, it's very consistent with what we were proposing in that it has to be scientifically based, independence and there needs to be peer review. All of those features

are included in their counter-proposal.

I do want to get a sense of the PPDC as to whether or not you're comfortable with us going down this path.

MS. LEVINE: The time line is also pretty comparable.

MR. JONES: The time line is consistent. It's very marginally different, I have to say, but it's different.

Pat?

PAT: Jim, just to say that I think that Bill Stokes has responded very constructively at ICCVAM to the ideas that you put forward in your letter. They seem to seriously regard it as a model where you can pick off the low-hanging fruit, if you will, the -- instead of broad validations, really go after narrow product niches where the data are quite robust, and you really can use these methods for the regulatory purpose that you guys need; namely, to make the category decisions on toxicity labeling.

I think, as Tina said, I think they got that, that it was clear for them really for the first time that that is the narrow objective here, instead of what they normally do, which is a much broader validation across all product lines. So, it was a very good session at NIH, and I think those of us who have been involved are conscious of the fact that probably those here don't want to spend 90-minute sessions looking at harvested eyeballs anymore. So, we are going to try to work this, you know, offline and appreciate your continued kind of leadership on this.

MR. JONES: Julie?

MS. SPAGNOLI: I guess just for clarification sake, what were the key differences in what we -- in what was proposed and then what they came back with as an alternative?

MS. LEVINE: I think we were going to do our own workshop, and we were going to -- I think there was also a step in which -- as a

result of the -- that the results of the workshop might lead to an interim policy, and then -- while the ICCVAM was considering it. That's sort of the -- I think those are the two major differences.

PAT: Well, I guess -- yeah, I mean, I think that's right. I think ICCVAM regarded the workshop as somewhat repetitive. I think it is very important to continue to keep our eye on the ball of if the science hangs together, as we think it will, in the technical review at ICCVAM, your commitment to considering an interim policy at that point, because the ICCVAM process, to be fair, can from that point on be a lengthy one.

MR. JONES: Is that it, Julie? Is that --

MS. SPAGNOLI: Yeah, I just...

MR. JONES: Troy, do you want to --

TROY: Yeah, Pat got to my point. It was just that the -- we had talked about an interim policy, and that seemed to have been

excised from the slides here. So, just to be sure that that's still being considered.

MS. LEVINE: Yeah, that wasn't part of the ICCVAM proposal, which you might expect, because they sort of see themselves as the keeper of the final say on this, but it also looked to me like with the ICCVAM proposal, there may be some steps that could removed, and it might be a -- it might be faster to the ultimate conclusion. So, depending on the timing, whether or not it would be necessary is the question.

MR. JONES: Erik?

ERIK: Just a quick question out of idle curiosity. Are we really -- what are the methods that are seriously being considered in maybe two sentences?

MS. LEVINE: Roger, do you want to speak to that?

UNIDENTIFIED MALE: Roger Curran from IIDS may be the best person to --

ERIK: I am not looking for a long

exigis, just --

MR. CURRAN: I'll try and keep it very short. There are multiple companies now involved in submitting data who are interested in this project. So, there are -- from what we originally thought might be just a couple of alternative methodologies, there may be now one or two others that had been company-specific up until this time.

In general, though, for the eye, it would be using an excised bovine cornea from a slaughter house as a model, using a reconstructed human tissue that's very much like the cornea but made out of human tissue, and the third method would be an instrumentation that measures metabolic capacity of the cell and its changes. That would be for eye.

And for skin, it's likely that it would be a human -- again, a reconstructed model of human skin and most likely a number of clinical trials as well, so that the non-animal part would come directly from the human. That's

likely the set of data that is going to be available to us.

MR. JONES: Okay, well, you know, I think actually your question and the answer highlights why, although the issue may seem very esoteric, and I have certainly gotten the sense of the PPDC that you don't like spending too much time, I think it is important for us to keep this in front of a broad stakeholder group, even though it's a relatively narrow group that's very actively engaged in it.

So, we're going to proceed down this path in a way that we do keep you all posted on what we're doing and where we are.

Butch?

BUTCH: The slides show an issue that is out there but not resolved, which is the joint ICCVAM/SAP review as opposed to a two-step process. Are there any advantages to -- could we have one minute on the advantages and disadvantages of a one-step versus a two-step process?

MR. JONES: Personally, I think that if there's a lot of consensus, that a one-step process is adequate. If there's some degree of dissension occurring, I think you then may want to take it to an SAP, but -- again, those choices haven't been made, but that's what my thinking would be.

MS. LEVINE: But I guess that option would be if we had some people on the -- from the SAP on the group, and we could always do that, even if we had a combined, we could still have another.

And my understanding from the ICCVAM is they have -- at other times they have made decisions or recommendations, and then it's gone to the SAP, and it does -- it does sort of broaden the review, you know, you get different perspectives, you get different -- it can sometimes enrich the input.

MR. JONES: Um-hum. (Inaudible.)

UNIDENTIFIED MALE: I'm just curious if this very narrowly focused project has

opportunities in the future for expanding to some other data requirements.

MR. JONES: It may well. It may well. I don't think we've got anything right now in front of us that it -- that I would say is here's the next one down the chute, but that's one of the reasons I want to keep it as public as it is, because if it does, I think it's going to be more and more important for it to be done in a very public way.

Okay, thanks.

All right, our next topic this afternoon, PRIA, the Pesticide Registration Improvement Act, which we've talked about pretty extensively at our last session, one of the work groups that came out of that was the PRIA Process Improvements Work Group, and what we are going to hear this afternoon is a report out from that work group, and Marty Monell, the deputy director for management in OPP, is going to lead that discussion.

UNIDENTIFIED MALE: Excuse me, Jim?

MR. JONES: Yeah.

GARRETT: Do you have additional copies of the six and three handouts? I don't have any in this packet, and I think there are others that don't have it as well.

MR. JONES: Of this particular presentation, is that right?

GARRETT: Yes.

MS. MONELL: There is no -- there is no handout for this particular session.

GARRETT: Oh, okay. Well, that would be why.

MS. MONELL: There is, however, a handout for the very next session. Margie? Okay. So, but thank you for reminding me, Garrett.

The Pesticide Registration Improvement Act of 2003, PRIA as we fondly call it, requires the Agency to look for process improvements in our registration processes to enable us to meet the time frames envisioned in this bill. So, we came to the PPDC last spring and sought some

advice as to how we should proceed. We had already done some internal process adjustments, if you will, and had received a lot of recommendations from the coalition which led to the -- which was a group that led to the actual passage of PRIA, but we didn't have a formal process for developing a process improvement plan, if you will.

So, we came to the PPDC, basically asked for guidance, and were told that the best route would be to involve a group of stakeholders, those which are most directly impacted by registration decisions, and with that charge, we set forth and put together a work group. We have about eight, nine -- ten members representing industry, we have two representing public interest sector, and several members of the OPP registration staffs.

Today you are going to hear from Rick Keigwin, who basically chairs the work group, and from Howard botch in the case which Veridien Corporation, Greg Watson from Syngenta, about

some of the processes that we have come to some agreement on for improvement. I should also note that although they weren't able to attend the couple of meetings, Erik Olson and Caroline Brickey are also members of this work group, have been -- have had access to all of the minutes of the meetings of the work group and an opportunity, obviously, to weigh in on anything that they saw as problematic from their perspectives.

So, I'll turn it over to Rick.

MR. KEIGWIN: Thanks, Marty.

I thought what I would do is first talk about some of the process improvements that the Agency has started to implement and then talk about what we've been doing within the committee itself and then lay out what our next steps are.

Howard and Greg are going to talk about some of the initial sets of recommendations that the committee as a whole have come to and some plans to begin to implement those within the process.

As part of meeting this objective in the statute, the Agency looks at not just what's coming out of the work group and through the PPDC as opportunities to find process improvements, but we're also looking internally to see what, based upon our experiences, could also make the process work better.

One of the first steps that we've taken is we are actually doing some benchmarking type of exercises. So, for example, we've been meeting with the Food and Drug Administration to find out when they implemented the Prescription Drug User Fee Act, PDUFA, what types of changes did they make in their process to make their system more efficient.

We a few weeks ago traveled up to Ottawa and met with the Pest Management Regulatory Agency. They have had a fee-based system for the past six or seven years, and they, too, have been looking at efficiencies in their process, largely around information technology and how do you employ that into your

process, and we learned a great deal from them on that most recent trip. I think there's a lot of opportunity for collaboration with them, particularly in the IT arena, to improve the efficiency of the registration process domestically.

We also decided that we had to improve our current tracking systems. The open system that I think we've talked about here on previous occasions, in order to be prepared for when PRIA went into effect in March, we had to make a number of modifications to that system in order to allow us to track the incoming applications, know what the decision times were, be able to use that system to generate bills for the new actions that were coming in, and all those improvements have already been made.

Another area that we've been working on is speeding up the initial cataloging and screening of the studies as they come in. We've actually been very successful in reducing that initial up-front process down to about a five to

ten-day process. That improvement gives the regulatory divisions an opportunity to more fully screen the applications before the decision times actually start. So, you have an administrative screen, and then you can actually begin to have a bit of a substantive screen to see is the application complete, is it in good enough shape that we can actually begin the substantive review?

Then we also have adopted some screening procedures whereby -- and this is actually something that we learned from the Canadians -- is they actually moved some of the their regulatory staff into the up-front process is unit or front-end type screening unit so that these 90 categories of actions, you had regulatory experts who can better categorize those types of applications, and so we have set up procedures where our regulatory staff go into the front-end processing unit every day, and so --

(End tape 3-B.)

MR. KEIGWIN: What's come out of that are some checklist types of things that our staff are using, things like completeness checks, are all the forms there, are the labels there, does the label match what the data say, some initial things that if we have the application correct in the first few days, it streamlines the process later on.

We have also developed a more improved coordination process with the IR-4 program, particularly surrounding the submission of new food use applications for minor uses. Historically, what would happen is that IR-4 would submit their tolerance petition, and then sometimes, but not all that often, registrants would come in with their labels at a later date. What we have now worked out is a system whereby IR-4 coordinates the entire submission, so that the tolerance petition and the labels and the registration application all come in at the same time. We actually think that that is very -- it's helpful to us, because we have a complete

package up front. It actually, in all likelihood, will streamline the registration process so that growers will get access to these products more quickly, because we won't be having to wait for the registration package.

And then finally, we've begun to institute some scoping type exercises up front in the review process, trying to tailor the review process to meet what the application is about.

With that, we've begun to implement some revised evaluation procedures, particularly in the fast-track amendment type arena. Historically, we would review an application, and if there were deficiencies, we'd write a letter and we'd communicate that back to the registrants, and then that would close out a cycle, and then we would have to start a cycle up all over again.

What we're starting to do is, particularly in the area where there are minor deficiencies, we are calling the company and

saying, if you can get this issue corrected in a very short period of time, say less than a week, we can continue on with the review process, and I think that makes things a lot better. We're doing similar types of things in the end use product registration arena.

One of the areas that we're still working on, and this is -- will actually be a major focus of the next work group meeting that we have later this year, is in the area of a new evaluation process for new active ingredients and new uses. We're looking for areas where we can broaden public participation in the registration process. We're looking -- we've currently looked at the model that's used in reregistration for public participation, but we're also looking at other opportunities to involve a broader group of stakeholders in the registration process.

So, to date we have had two work group meetings. We had an initial meeting in late August where industry came forward, and they had

about 14 -- 13 or 14 process improvement areas that they thought were of high priority for consideration. The Agency also put forward about six or seven additional process improvement areas, and we looked at how similar or if they complimented each other in any way, and in large part they did. So, we were able to actually narrow those down as an initial set to about seven initial process improvement areas to focus on.

From that, in mid-October, we met again, and we fleshed those out a little bit more and began to identify some -- put together some work plans to focus on at least a couple of them, areas where the Agency could develop improved guidance for registrants or areas where we could improve the evaluation process in the area of label reviews.

So, with that, I am going it turn it over to Howard, I think, who is going to talk about a couple of those areas.

MR. BOCHNEK: Okay, thank you, Rick.

The pesticide-producing entry, represented by a broad coalition of registrants and trade associations, agreed on, as Rick said, 14 process improvement proposals. The 14 areas where the need for process improvements have been identified span all three divisions across BPPD, RD and AD. While there may be some further refinement as we move forward, the industry has further specified the seven highest priority issues. Concurrently, the Agency has identified five areas where they believe that process improvements are most critically needed.

I'll be summarizing the concerns raised by the Agency, which I can tell you, as Rick indicated, are shared concerns of the industry, and I'll address one of the industry's seven highest priorities. Greg Watson, who has been a leader in this entire process on behalf of all the sectors of the industry will be speaking about the additional priority concerns.

The Agency's five concerns can be summed up under the titles of Improving the

Quality of Applications. Specifically, the Agency has identified the need to address, number one, the incomplete data submissions. Secondly, the Agency has been concerned about applicants needing to meet the requirements of PR Notice 86-5 with regard to standard format for data submissions. When data submissions come in that are not in the standard format, it takes time, creates problems for the Agency.

Number three, the need for applicants to improve the documentation that they provide with their registration applications. Fourth, the Agency is concerned very much with the filing of incomplete application forms. And again, on all of these areas, these are areas that the industry is also very much concerned about, and just because the Agency is the one that raised them, it's not to believe that the industry isn't equally as concerned.

Fifth is an item called, for lack of a better explanation, better labels. This is somewhat of a complex subject. Better labels

impacts on the application review process, it impacts on registrant needs and expectations, and it certainly impacts on the commercial and public users of agricultural and household use, herbicides and pesticides, as well as medical office, hospital and home use of disinfectants and other anti-microbial agents. If you can't understand from the label what the product is for and how to use it, the label isn't very useful. And again, while the Agency is the one who has raised this issue, the industry is vitally concerned with the same problem.

The industry agrees that the process improvements that have been identified by the Agency are ones that need to be acted on as quickly as possible jointly by the Agency and by the industry working together.

One of the highest priorities identified by the industry is the matter of product chemistry reviews. Of particular concern is the number of cycles that occur between the registrant and the Agency, even

where there are cases of minor deficiencies. The Registration Division has a new process that will probably help a great deal in this area. We anticipate that progress will be made under PRIA and the other divisions as well.

Registrants need advice and training on how to complete confidential statements of formula, and that's an issue which from personal experience I'll tell you also applies to the completion of data matrices as well. We need to know from the Agency what they're looking for, how these complex -- at least from an industry side -- complex forms need to be filled out in such a way that the Agency understands the information that we're providing.

Registrants would further like further guidance with regard to the use of inert ingredients and how they can be used in various types of formulations in the products that we make. Both the Agency and the industry have data and examples to support each of their concerns. So far, we see good progress towards

resolving all of these issues and in the direction of implementing the process improvements that were desired and foreseen by the implementation of PRIA.

We thank you for your continued concern, your encouragement and our support in our progress towards addressing these vital activities.

MR. WATSON: Thank you.

What I'm going to try to do is just give some highlights, again, from continuing on on some of the process improvement areas that we've discussed, but what I'd like to say in the beginning, as we said in a PRIA workshop that was held last week, we certainly congratulate OPP on how open and transparent the process on PRIA has been to date, and also the level of energy that has been very evident as they've gone forward, serious implementation consideration there. So, the group that has been working on this is to be congratulated.

I think one of the topics I would just

like to highlight again was the consistency in the label review, and as Howard mentioned, EPA's listed this as a topic of concern for them as well, particularly where use information was difficult to be captured so it could be fit into the risk assessment process.

We initially agreed in the group that EPA would go back and do something like a rejection rate analysis where they looked at label rejections and the reasons why. After further discussion, the thought was that that would be too resource-intensive versus the benefit that could be derived, so we adopted an alternative plan where we'll come back to EPA within the group and the surrounding coalitions and trade groups that are represented to come to EPA with examples where we believe the label review manual has some potential areas of disagreement with PR notices or other policies or 40 CFR.

We also have agreed to come to the committee with a listing of examples where label

categories may need further support in terms of how they would be best described. For example, from the Registration Division would be turf use. It's not corn, and there are some peculiarities about particular use patterns with turf that may need some further elucidation about what needs to be on the label.

Our goal is to also identify a group of those who are BPPD and AD, such that we would pick or prioritize three to five for each of the divisions for further -- bring them forth for further consideration.

We also have agreed to come forward with some specific examples where there have been differences in label reviews done by EPA, and again, we talked or I presented an example that the term "selective herbicide" suddenly, for a very short period of time, became something that was of concern to EPA, was removed from labels, and then after further discussion, was able to be placed back on. So, again, it's just an example of how an issue came

up and was eventually resolved, but again, that's one of the examples we might talk about again.

Okay, so that was really just a general area about one of the label improvements that we have brought and discussed in the group.

Another topic was registrants' interest in having status of pending applications be more visible. The auto-notification of the billing under PRIA to the registrant has been a very good process, and it's led to an interest from the group to have that expanded to other areas, particularly the time line of where the PRIA date actually starts.

EPA is working on this issue. It will take a lot more infrastructure to bring forward, and there are some technical issues, but I think there's a commitment to make milestones in the registration process more routinely notified by electronic means.

The next topic that I'd like to bring forward that we've discussed is a communication

on data evaluation records or DERs and end points as they are being selected during the registration process. There has been an issue where DERs have not always been available to the registrants after they have been completed, and in fact, to the point that some registrants have actually had to go through the Freedom of Information Act request to find -- to get those.

I think there are -- if you look at some of the improvements that Registration Division has brought forward that Rick mentioned, there is a proposal that those DERs and those risk assessments would be posted in a public docket at the end of the process, and I think that certainly is something that is worth looking at, certainly would provide more stakeholder access in that regard.

There is also a mention in the process improvement from Registration Division about, quote unquote, "problem DERs," and I think that's also important. As issues are identified in the registration process, that they are

brought forward and communicated, then you can begin to work much more quickly toward reaching a mitigation or working through some science issue that might be there.

And that leads, again, to one of the biggest time lines in a registration process, is it comes about if there's disagreements over end points that were selected in the process, and I think that's another place in the public participation process that, again, Rick mentioned earlier, to try to find a way forward in terms of where those could be identified and communicated earlier.

I'm almost finished. There were 14. We're only going to talk about seven.

Well, the other ones of interest, I think particularly to EPA and industry, is electronic submissions. One of the things that has been put in place but not universally adapted by the registrant community, nor within EPA, is electronic labeling review, and those tools are available, and I think that's, again,

one of those places where industry and EPA -- that just needs to be how we do business now, and I think we need to work on setting up and moving forward on that.

At the PRIA workshop last week that was held, it was reported -- and I was very happy to actually hear it -- that all the active ingredients, new active ingredients, that were submitted to EPA in fiscal year 2004 were submitted electronically or had some part of their database in electronic form. I think that's a huge step forward compared to where we were, and it just shows the power of where EPA was able to stabilize the formats and the templates that they wanted, and industry was able to provide that. So, we need to continue that.

And along that area, study profile templates, which are actually draft data valuation record, they follow what EPA would produce in that area. That's also something that is strongly supported the industry and by

EPA. EPA will certainly still do the review of the study, but it helps the logistical process of moving that forward.

I think one of the major concerns that was raised at the workshop last week was that even though EPA's made a lot of progress in that area, OECD now has launched into this fray, and it looks like they're running at a pace that may be a little bit ahead of where we in the U.S. would like to see it go. We certainly want to get there in the end and have a harmonized format, but there's a concern that they have not taken into account the progress that's been made to date within NAFTA.

And finally, just a couple sentences about endangered species. This is certainly an area that EPA's working hard on to bring forward transparency and process to that. It's just that we, again, within this group wanted to highlight that that is a needed area where we need to move forward; how the registrants submit to support an endangered species assessment, how

does OPP plan to follow the process in terms of producing endangered species assessments on a routine basis. Those are two real questions we need to continue to work on.

And certainly there's a critical need to continue to progress and update the eco-risk assessment policy within OPP, because working at the screening level and a terministic level, and each assessment is really not going to resolve that -- those issues. Certainly the case studies that have been put forward, the 2(4)(D) case that's been adopted, and reregistration will help set that as a model and will help everyone understand from both sides what the targets are.

With that, that's all I intended to say. So, thank you, Rick and Marty.

MR. JONES: Gary?

GARY: That was very interesting. The joint workshop was alluded to several times, and I know Ray was heavily involved and a lot of us in PPDC were involved with it as well. It was

excellent in my opinion. We had industry, public interest groups and the Agency all working together, and I think we accomplished quite a bit.

What was particularly interesting from my perspective was on the second day, we broke out into three different groups, those who sort of needed work with AD, those who needed with RD and those who needed the biological BPPD, and I was extremely impressed. I went to Janet Anderson's group, the BPPD one, and saw some of the things on the tracking systems, which I was very excited about, and that's what I'm bringing up now, is the tracking system.

I know it was alluded to earlier, but whatever that can be done internally from OPP, the tracking system, and then certainly letting us know what's happening is something which we would definitely want to encourage, and I saw Bob Tarla had some interesting things in Janet's organization which I thought was excellent, and maybe there needs to be more consistency within

your divisions within OPP, but certainly from a registrant perspective, we would love to see that followed up on.

MR. JONES: Thanks. Julie?

MS. SPAGNOLI: With regard to labeling, I think another aspect of this that was discussed with the work group and I think is relevant to bring up here is also the need probably to involve the states in some of these -- in some of the label issues, that there is already systems in place where the states can identify some problem labels or problems with labels, and that can, you know, sort of be part of this process as we look at, you know, what are some things we can do to help from both the registrants and the Agency side for better labels, more useful labels from the registrants and more consistency in review I think from the Agency, and identifying maybe what types of labels need more guidance or need some kind of more consistency.

And I think we also identified the need

for when a policy decision is made with regard to labeling, because a problem's been identified with a particular label or some particular use pattern, to make sure that that gets documented somehow and made available so that that can then be used by other registrants or other reviewers so that we can get more consistency in decisions, because I think sometimes a decision is made on a particular label, but then nobody else knows that that decision was made, and so that's where some of the inconsistencies sometimes come out.

But I think we really do need some inputs from the states on the labeling issues as well and also what the states -- how the states use the PPLS, the labels that are posted. There has been some discussion with that as well, to make sure that that is used in a consistent manner.

UNIDENTIFIED MALE: And in fact, what we're trying to do is for the next meeting of the work group, we're trying to align it with

either a meeting of SFIREG or a meeting of the POM committee, so that states already in town, and then we'll add on a couple of hours. That will be a joint meeting of POM or SFIREG and the work group.

MR. JONES: Thanks. Shawny?

SHAWNY: Greg, you said something about -- right at the very end there that something -- I'm assuming the 2(4)(D) risk assessment acted as a model for endangered species. Could you elaborate on that?

MR. WATSON: Yes, there has been an agreement within SRRD that they will work on 2(4)(D) as a case study, where it's actually very, I think from what I understand about the scope, it will be very similar in some ways to the workshop that actually was held yesterday on how EPA will do the risk assessment that leads to the endangered species finding.

2(4)(D) is going through reregistration right now, so as part of that process, again, they'll use that example as a case study that

then can be presented, you know, after the fact to show us the pathway that will be utilized. And again, I think that will be very helpful to all players, registrants as well as participants or other stakeholders.

SHAWNY: Can I just add onto that? Do you know if in that meeting -- and I should review that as well -- but if it was also raised to use the other -- to look at the other chemicals that are used closely with 2(4)(D), such as MCCP or the other combined -- you know, that are usually associated with the actual product and looking at endangered species?

MR. WATSON: I don't know about that. As far as I -- all I've heard is that it's intended to be 2(4)(D) specific, because that's within the action, as I learned yesterday, the action definition will be bounded by the active ingredient.

MR. JONES: Anyone else? Yeah, Dennis.

DENNIS: Rick, I think you mentioned one of the upcoming focuses is going to be on

public participation in new active ingredient assessments. Could you go into that a little bit, describe what you're thinking about doing there?

MR. KEIGWIN: We are looking towards the model that we have used in the reregistration process, you know, whereby there are different points in the process where snapshots in time in either where we are with the risk assessment or taking comment on risk management have been utilized in the reregistration program.

We have been working within the work group on how and what parameters of that type of a process would fit within registration. Industry is actually working on a proposal for how you might do that. Currently there are opportunities within the existing registration process for public involvement. We do -- we are required by statute to publish notices of filing, that we have received new applications.

We also publish the industry risk

assessment that's submitted in support of food use registrations. We don't often get comments on those. And one of the things that we've already talked about doing is at the end of the process, not only putting all of the data evaluation records in a public docket, but also putting the risk assessment into the public docket. Those things are available. We don't readily make them available currently, but if we were asked for them, we would provide them.

Now, the idea that the Agency has put forward is that we would more routinely include those in a docket so that people could have access to those, but we haven't come to any firm conclusions on how we might do this. We're really more in the exploration phase at this point, and again, if it's something that the states are interested in, I think that could be another agenda topic for this next work group meeting.

MR. JONES: Erik?

ERIK: Yeah, I just had a question.

One of you mentioned something about what to do with "problem DERs" and what to do when there's disagreement over end points. I think maybe it was Greg that said something about that, but could you explore that a little more about exactly what you're talking about?

MR. WATSON: There are many times, particularly in a new active ingredient, where let's pick a clear-cut example where there's been migration of an OECD study protocol and that you may have done a study that, for example, because of the time line to development that was, you know, by an old protocol, well, EPA expects to see something different because the protocol has changed. There might -- that might be one instance.

There also might be an instance where there was one of the parameters missing for the study that EPA says, wait a minute, we think this study doesn't meet our guideline, or you could actually end up with an end point from a study that would create an issue in the risk

assessment for the registration action.

It's in those places, particularly the last example, where EPA communicates with a registrant that you have obviously a lot of discussion and potential for disagreement, and that can go in a lot of cycles, and that's the points we were trying to make, is that if we're going it meet the PRIA time lines, those need to be identified and communicated as early as possible in the process so you can work through, you know, what the issues are. Is it, again, a simple protocol? Is it -- and so I think that's the only point.

ERIK: Well, I guess my concern would be that if there's sort of a nonpublic process where there's debate about what end point we are going to use, you know, I don't think that's appropriate, but I'm not sure I'm hearing correctly what your proposed solution is to that.

MR. JONES: Erik, this has actually been one of the areas that there has actually

been a little bit of disagreement currently between the Agency and registrants. What we -- what the Agency has maintained during the work group discussions is that where there is disagreement, we actually think that there should be a public process surrounding that, and so as part of the -- that involves more than just the Agency unilateral/bilateral discussions with the registrants, and what we have to look for and what we're hoping to do is find ways within the FIFRA context that allow us to talk about things predecisionally, to allow public participation into those types of disagreements.

ERIK: Well, I will say PRIA, you know, it was anticipated that that kind of thing might happen, and if it's a big enough deal, then it would, you know, potentially go into a parking lot, and there would be a debate about that, not subject to the deadlines. If it's not a big enough deal, then perhaps you can deal with it through public process. My concern would be that we not have bilateral discussions about

issues of that import. There should be some kind of public process.

MR. JONES: And that -- that's fair.

Okay, well, thanks -- oops, I'm sorry, Shawny.

SHAWNY: I just have to say, this is the first time I'm hearing of this, of 2(4)(D) being used as a model for endangered species, and I'd have to say I thought that there was something about Medichlor perhaps being used also as a model -- no?

MR. JONES: That was an example we used yesterday at a workshop to walk through --

SHAWNY: Okay.

MR. JONES: -- how we are -- we plan on doing endangered species analysis.

SHAWNY: Okay, all right. Well, I just -- I raise this just because as we know, there -- you know, there has been a lot of work done on 2(4)(D), and of course, there's a lot of issues with it showing up in very low levels, of course, as an active ingredient on its own but

that it is still very rarely used as an active ingredient on its own, that there's -- it -- I just think there would be a lot of contention with using such a high-profile chemical, and you might want to take that into account.

MR. JONES: I appreciate that.

Well, I think that the -- it's important that we keep in front of the PPDC process improvements. I'm very committed to -- have been pre-PRIA and will be post-PRIA -- about process improvements, in particular as they enhance our efficiency, and that's how we're engaging in that process. I think it's -- I believe that everybody around the table wants us to enhance efficiency without compromising safety, and I think one of the ways in which we can assure that happens is by having transparency around that. So, we will continue to bring these issues to the PPDC prospectively. So, thanks to the group that's been working on this, and we will now move on to the next topic, which Lin Moos, from the Field and External

Affairs Division, is going to do some follow-up on an issue we brought to this committee at our last meeting around consumer pesticide label improvements.

(End tape 4-A.)

MS. MOOS: Okay, I want to update folks on where we are on the status of the consumer pesticide label improvement project, and the first thing I better start out by saying is everyone was just talking about label improvements and label problems in this PRIA discussion. This is a very, very tiny, tiny sliver that we're looking at here. We're not trying to solve all of those problems, and we're not going to hopefully get into most of them in the context of this group. I think there would be other fora to deal with those.

At the last PPDC meeting, we had a panel -- we had panel presentations and then an open discussion about improvement of labeling language, and as you recall, Paula Bodie's presentation presented boilerplate language of

"do not contaminate water while disposing of equipment wastewaters," and she posed that statement, I guess the plain English statement of, "rinse spreader over a patch of healthy turf so that the run-off does not flow to a curb, gutter or stream."

During the open discussion that we had after that, you as a group thought that Paula's presentation really made it clear that we needed to work on improvement of consumer label language and that this was a project that the PPDC should undertake.

So, last month, Margie circulated a submission statement and a request for work group participation for a subgroup to work on this consumer pesticide label improvement project. I hope you've already read the mission statement. It's been sent out to you multiple times. I did bring copies. That's what's being passed around. You don't need to review that now, but you know, it's available.

But the mission statement principally

had two goals. The first goal and the principal goal was to improve the consumer understanding of safe use, storage and disposal and the environmental and health information on household pesticide product labels. Improve the readability of labels, you know, make people -- make them understandable.

Our second goal is to design a program that can be easily implemented by EPA and the registrants so that we ensure that the registration transaction costs from going forward with any new program for label improvements is minimized.

There were four charges to the work group. The first charge was that working with EPA and stakeholders, identify problematic label language that's used on pesticide products, and again, this is language such as the "do not contaminate water when disposing of equipment wash waters." The identified language might be boilerplate language that was suggested in REDS or other standardized equipment use phrases on

consumer products.

The work group was then asked to prepare a standardized, easy-to-read alternative -- a menu of standardized, easy-to-read alternative language that registrants could place on the consumer products as an alternative to the current technical language. What we want to do here, again, is develop label directions that consumers can read, understand and follow, and the objective for this work group isn't to make safety claims about particular pesticide products, but again, work on the plain English.

The work group was also asked under this mission statement to recommend product criteria that can be used to limit the use of the proposed label language to products that are sold exclusively or principally to consumers. We don't want to take this new label language that would be a replacement for the technical language and put it on professional products or put it on agricultural products. The focus here

is getting to the consumer.

And the fourth charge to the work group is to consider whether there should be further consumer education initiatives that should be undertaken, particularly designed to increase the percentage of American consumers that read their products before pesticide use.

In response to the solicitation that was sent out, we had a number of PPDC and non-PPDC members offer to participate on this work group. We have a state official, an extension official and a very large number of industry representatives that have raised their hands.

It's important here, we need a balanced and a diverse group, which includes representation of consumer and environmental interests as well as industry interests. We have gotten one consumer organization on board. I'm pleased to be able to say that, but we don't have any environmental representation, and we really need some assistance from you folks to

get additional consumer environmental nonindustry people on board on this work group so that we can establish a diverse work group and initiate the work group and start working on things.

So, what are our next steps? As we're moving forward to balance the work group and finalize the list of participants, there's still some things we can do to move forward. Within the next couple of weeks, I expect to distribute a solicitation for problematic standardized language from PPDC, EPA staff, ATCO, ABSI and other interested stakeholders. I'm going to request -- assuming I get this out within the next couple of weeks, I'll request that we have got submissions by mid-November. Hopefully, by that point in time, we are going to have a balanced work group so that we can really initiate the work group efforts on the project.

My plans would be then to in December electronically distribute the list of candidate problematic languages that have been submitted,

that we've looked through, that the work group can review for consideration. I'd hope that we could convene the work group in January and sort of determine our path forward from there.

There's a number of things the work group will need to do at that meeting. We will need to select the problematic technical language for the work group to address. I don't know if we'll have 15 candidates, if we'll have 20 candidates, if we'll want to pick five candidates, if we'll want to pick ten candidates. We'll have to see what we get.

We'll need to determine the process for developing the menu of alternative, easy-to-read language, how we're going to go about doing that, are we setting up you subgroups to do that, teams to do that, are we breaking things apart, how we are going to develop that.

We'll need to determine how the work group is going to develop recommendations on how to define or distinguish the consumer product category that this program would apply to, and

we're going to determine how the recommendations are made by the work group and the need or the type for future consumer education initiatives. So, those are the things that the work group would be looking at and sort of figuring out how we are going to move forward with this project.

Hopefully, at the spring PPDC meeting, the full PPDC meeting, maybe we can have a menu of alternative language for a number of these technical phrases that are currently used on consumer products, perhaps recommendations for consumer distinguishing criteria and recommendations on the need for consumer education initiatives to bring back to this full PPDC for consideration.

So, right now, I'm looking for some additional participants on the work group and get us a more balanced work group so that we can move forward more formally. And also, look for the solicitation. It should be going out in a couple of weeks.

Do folks have questions?

MR. JONES: Julie?

MS. SPAGNOLI: Well, this is just a comment. I don't think we should limit the scope to just problematic language and alternative language, because I think what -- the way we kind of looked at this issue is with consumer labels, you know, traditionally labels were developed with an eye towards enforcement, and I think with a we've come to realize with consumer labels is perhaps it's not so much an eye towards enforcement as an eye towards education and looking just for ways to better communicate safe, proper use to consumers instead of just, you know, having a label that can be enforced, because typically it's not an enforcement issue as much as an education issue.

So, I think -- you know, I think there are -- you know, looking for problematic language and alternatives to problematic language is good, but I think also, you know, are there circumstances of language that has not been allowed, it's not something that's on there

that we want to change, but something that we think would help consumers but hasn't been allowed to be used, and also to look for those kinds of examples and just, you know, looking for, you know, how -- you know, what are some better ways through labeling that we can educate consumers on safe use and identifying -- you know, what we kind of find is we know that consumers want to be safe, they want to use products safely, and how can we best communicate that?

And as you said, it's not about making safety claims, but it's about encouraging safe use and helping them understand what are the safe uses of a product and how to use it safely. So, I think -- I just think we should make -- not try to limit ourselves just to finding problematic language and coming up with alternative language.

MR. JONES: I agree with that, Julie. I think that it's maybe just a bit of semantics around -- the way I read the mission statement

is very consistent with the way you've described it.

Well, we -- John?

JOHN: Yes, to follow up on what Julie said, I wonder if the approach that you're thinking about is going to get you the result that you want. You're asking for participation from various groups here to represent different sectors to come up with a result, but it seems that what you really want are people that are professionals in certain fields, like communications and education, and you could have that within your own staff that specialize in those areas.

And I'm wondering if you're also thinking in terms of doing the usual thing when you're trying to figure out what does the public or what does a consumer understand when they read a certain statement, and to do that, you do things like focus groups rather than having, you know, representatives from different sectors look at language and try to decide what's best.

I mean, that's the first step, but then you have got to take what they come up with and see if it -- you know, test it before it goes to the field.

MS. MOOS: I think some of the industry people that have been proposed for participating on the panel, in fact, have that technical expertise and have been brought to the table for that particular reason.

MR. JONES: And so does the Agency and I think so do the states.

MS. MOOS: Yeah, yeah.

MR. JONES: Dennis?

DENNIS: Yes, I would just like to follow up on Julie's comment about the need for better education and understandable labels, and I think we all agree with that. I think probably from a state perspective, the decision to not also be trying to develop label language that's enforceable raises some questions for us, and I guess I would like to ask the Agency going into the process whether one of the

considerations that you will want to be on the table is to be working towards language that's both helpful for understanding as well as enforceable or whether enforceability is something that would not be given a priority.

MR. JONES: Personally, I think that it's not an either/or, that it's specific to the language that you're talking about. There may be certain things on a label that -- and that's why I think we want the states in this group -- that nobody would view as being important to be enforceable, because no one would ever dream of enforcing it, and other things which they may see as being very important to be able to enforce, because they have experience trying to enforce it.

So, I think that you have to bring -- that we want that perspective at the table, the importance of the enforceability of certain statements, and the lack thereof for other statements. I don't necessarily see it as a yes or no but more specific to the language you're

talking about.

DENNIS: Thank you.

MR. JONES: Erik?

ERIK: Yeah, I just reiterate actually what Dennis just said, which is, you know, I think you can have and, in fact, it's actually better to have an understandable label because it's more enforceable if it's clear than if it's very obtuse. So, you know, I think the two should go hand in hand.

And the -- I guess I have a question as to whether the Agency's thought about whether you have a reading level that you're targeting, because I know we have been involved in some other agency activities where documents go out to consumers, and you run it through a standard reading level test, and it's 12th grade or higher, you know, second year college or whatever, and you know, the average reading level in the United States isn't even close to that, and I'm wondering, especially for consumer labels, if you're thinking about a specific

target reading level, like eighth grade or sixth grade or, you know, in D.C., I know the average reading level is something like fifth or sixth grade. So, is that an issue that you're looking at seriously, and are you going to have somebody that's an expert on readability, an academic expert on readability perhaps on the committee?

MR. JONES: I think those are good points that we need to -- that this group needs to ask of itself. I would expect that the consumer group participating and the companies would have some insights into this, because it's so important to what they do, but I think the question does need to be asked.

I saw -- no? Shawny?

SHAWNY: Yeah, I was just wondering, I know that a colleague of mine worked on a similar initiative with the Agency quite a few years back on this, and there was a similar type work group with symbols being proposed and all sorts of things. I was just wondering what kind of historical, you know, analysis was used or as

far as transferring some of that baseline data that may have been collected at that time.

MS. MOOS: Julie is one of the people that's raised her hand for this work group effort, and I know she was very much involved in the consumer labeling initiative. Do you want to --

MS. SPAGNOLI: There was a lot of work done. There was -- it actually went in two phases. There was an initial phase where we did some qualitative research with some focus groups, and that led to some changes in -- well, we did focus groups specifically focused on first aid language, and that led to the revisions that were made in the first aid language; also about the use of the term "other ingredients" versus "inert ingredients," some of these very general concepts were tested via focus groups.

The second phase of the research was much more extensive. We did actual quantitative research in three product categories. There was

hard surface cleaners, lawn and garden pesticides and indoor insecticides, and there was a number of different parameters that were investigated, you know, what kind of language people looked for, what they didn't read, what they did read, so that -- and it's all been -- all of that's been in a report that is posted on EPA's web site.

So, the whole report and all of the background materials is on the web site, and I think we are using a lot of that I think as a starting point for some of this and some of the changes that were implemented and some of the recommendations that were made, but for -- you know, for additional work that needs to be done.

Since I've got the -- I'll just make my other point. Just to respond, Dennis, I wasn't really saying that it's not enforcement. It's more from the consumer's perspective, though, that consumers don't read a label -- you know, unlike a professional user, they don't necessarily read the label from the perspective

of thinking of enforcement. In fact, one of the statements that was tested in this -- in the research that we did initially was the, "It is a violation of federal law to use a product inconsistent with its label," almost universally not understood by consumers. You know, we got comments like, well, that's just the same thing that's on the mattress, you know, that's what they thought. So, they --

UNIDENTIFIED MALE: That's where we got it, isn't it?

MS. SPAGNOLI: So, you know, when they go to look at a label, you know, as compared to let's say a PCO, you know, they're not looking at it from that standpoint. So, I think that's -- you know, but -- which is why from how the consumer's reading the label, I think we want to focus on educating them more than, you know, them knowing that it's against the law if I don't use it this way, because they just -- they don't seem to have that perception.

MR. JONES: Steve, and then I think we

were ready to move on. Is that --

UNIDENTIFIED MALE: No, Mary Ellen.

MR. JONES: Oh, Mary Ellen.

MARY ELLEN: Well, two points. First of all, Julie, I understood what you meant, but you'd be amazed at how many neighbor-versus-neighbor complaints we get involved in where pesticides are used to get revenge on the bamboo or the prize rose bush, where we're forced to try to explain the label. So, I knew you didn't mean -- it's not a primary focus of anyone to do consumer labeling enforcement, but we do get involved in that quite a bit.

And to add to John's concern about the stakeholder or the focus groups, I was part of the consumer labeling initiative initially also, and I would hope that the information we have from that very extensive study we would --

MR. JONES: Bring into this.

MARY ELLEN: -- tend to use and bring into this whole process and build on that.

MR. JONES: Absolutely. Okay, Steve.

STEVE: I just have a real quick thought here, and this is I guess an alternative language that the group is going to put together. Is that right? I mean, it's not mandatory --

MR. JONES: They are going to attempt to do so and see if we can get a consensus around that and bring that to this group.

STEVE: I was reading the mission statement --

MR. JONES: It's hard to do, let me tell you.

STEVE: When I was reading the mission statement, I think that's what it says, so maybe that should be changed if we are going to go that way in some way.

MR. JONES: All right, thank you very much. And again, it is very important to have balance on this. We do have, thankfully, a consumer group willing to participate on this. I do think it's important to get someone from

the public -- from the environmental part of the public interest community, and we will continue to work with a number of you, if not yourselves, to help us find someone who meets that criteria as well. All right, thanks.

Okay, back to Marty Monell, who is going to walk us through some budget issues that relate to, in particular, our discretionary extramural dollars in the Pesticides Program but is going to give you a broader perspective as well. Marty?

MS. MONELL: Well, I just have to share -- I'm standing up here so I can use this little pointer that I borrowed, and on the ring, there is this picture of Wonder Woman, and sometimes I feel like Wonder Woman or I'm expected to be Wonder Woman, because I have to go get resources -- that's not easy -- and then I have to stretch them so that everybody gets what they want when they need it. So, this is a very appropriate tool for me to have borrowed.

We're doing the budget presentation a

little bit differently this year -- a lot differently this year. Usually I just sit up here and say, this is what we got, this is what we spent, and you don't really have a sense of the context within which we have to make some spending decisions.

So, I thought what I'd do this time is give you a picture of all of the funds available to OPP for the fiscal year 2004 for expenditure, and then we're going to drill down until we get to the level at which field programs and discretionary money is available to make decisions around.

So, here you'll see this -- this figure right here is the FIFRA -- you know it as the maintenance fees. Now, you probably are wondering, well, I thought they were able to collect $26 million in '04, and in fact, we were, but -- we were only able to collect $25.9 million just as a result of the billings, but the Agency takes about $2 million off the top for our leasing and utilities, for our buildings

and services kinds of costs. So, we're reduced right away from that. Then we have to set million dollars aside in sort of a little trust fund pot, if you will, to fund unfunded leave, to keep it in reserve in case any of these FTEs that are supported in this fund, if they all should retire, we have to have a way of paying them, and there is no appropriated dollars for that purpose. So, right away, we're down $3 million, and that's why that figure is a little bit less than the $26 million you may have had in your mind.

This figure right here, for those of you that were at the PRIA workshop, you probably heard me talking about us collecting $14 and a half million, and yet this is only showing $5 million. That's the money that we actually spent. The rest of the money is in the fund and is collecting interest until such time as we need it, and probably we'll be needing it soon to cover payroll costs. So, that sort of -- this is more or less the total headquarter OPP

funds available to us this fiscal year for expenditure.

MR. JONES: Last fiscal year.

MS. MONELL: Last fiscal -- yes, sorry, thank you.

So, you will see reregistration, we had 72.4. That includes our appropriated and the FIFRA maintenance fees. Field programs, 13 million. This figure actually includes this $5.3 million that we collected -- that we spent in -- I'm sorry, it includes $480,000 that we spent on the worker protection activities this fiscal year.

This figure right here, other, that's actually -- we get about a million dollars for Homeland Security efforts. We get -- we have a Congressional earmark for Hawaii. That's located in that little pot of money. And then we have a tiny amount for endocrine disruptor work.

This registration figure also includes about -- a little less than $2 million, which

through an anomaly of our maintenance fee law, we -- there's a little set-aside, a small amount of money for fast-track registrations. So, even though it's in maintenance fees, it comes for fast tracks. And this also -- this figure does include the PRIA dollars that were spent other than on the worker protection activities.

So, now you go to the next slide, which you'll see are smaller dollar amounts, so that's why I went through the litany of how we spent some of the FIFRA fund fees and the PRIA fee money. This is our actual appropriated fees. No FIFRA fund here, no PRIA fund here. And again, you'll see that reregistration is the highest amount, receives the highest amount of appropriated dollars. Registration is this amount, other, field. Field you'll see is smaller than the first one because of the money we spent on the work protection. Next slide.

Now we're going down into just a little slice of the pie from the previous slide, which is registration, and that should be funds, it's

not a separate fund for registration, and of that 41.2 million, this is how we spent it. As you'll see, salaries, consistent with the history of our program, is the largest expense in our budget.

And then working capital fund, that funds things like all of your desktop, all of our communications stuff, that's taken out, and it is a apportioned on a per-FTE basis. So, there is no discretion there. The Agency just takes it. We're billed for it and we pay it.

Contracts and expenses, that's about 5.8 million. As you see, that's -- that is a discretionary pot, but we have to use it to support our registration activities. So, when we -- well, we'll have that discussion after the next couple of slides. Next slide, please. Thanks.

Reregistration, again, the salaries is the bulk of what we spend the money on, 31 million almost, and then contracts and expenses. Again, this is a kind of a larger percentage

than the registration contract expenditures, and when this -- and contracts and expenses, that includes grants. It's all extramural expenditures; contracts, grants and interagency agreements, which will become important when we drill down a little bit further.

We're on the field program, okay. For field programs, this dollar amount right here includes $1.3 million in STAG money. That's a special pot of money that gets appropriated to us specifically dedicated for funding to the states and tribes. Again, we don't have any discretion on how that's spent. It goes through us and right out to the regions for distribution to the states and tribes. So, this is not a discretionary pot of money.

This, again, contracts and expenses, we're going to drill down, as I say, further. That obviously -- that's the extramural funds. This includes IAGs, grants and contracts, significantly more than the salaries devoted. So, in this particular instance, we use fewer

employees, fewer federal employees to provide services and support to our registration and reregistration program throughout the country. We use fewer FTEs than we do with the extramural dollars. Next slide.

This is the tricky one, tricky because I've not notes all over my paper and you -- just to help you sort of see it in the big picture. The regional SEE grant, there is a program, the Senior Environmental Employment Program that's authorized by Congress whereby we can -- we -- EPA, in particular, can hire retired folks to help us with our programs. They're more like contractors than they are -- they are definitely not employees, but they're more like contractor employees than they are any other sort of legal entity in our program or in any EPA program, but they are -- they're critical in the provision of services, both technical and administrative, throughout the -- throughout our organization and particularly in the regional offices. So, we fund a small pot of money to particularly

support in the regions our field program activities.

This pot of money, the ag initiative -- the ag initiative actually is only a couple hundred thousand dollars in this particular pot, and what this does is support the multimillion dollar agency strategic ag initiative that is basically administered out of Adam's office. These are just small little programs that get a little extra support from us. The big piece here is negotiating with partners -- whoever came up with these labels, I don't know -- but what it means is any time we give money to another state entity or federal entity, it gets lumped in with the negotiation with the partners.

So, in this category, we fund SFIREG, for instance, to enable them to have their meetings, and the largest chunk of this goes to USGS to support our work on endangered species and groundwater activities.

Environmental Stewardship Program,

$500,000 -- a little over 500,000 of this is STAG money, again, and again, not discretionary to our use. It goes to the regions and then out to the states and tribes. The rest of that amount, about half of it goes to the National Foundation for Integrated Pest Management, and the other half goes for risk reduction and is going to the American Farmland Trust essentially. I'm talking -- there may be other little small amounts given out here and there, but I'm just talking about the larger ones that are representative of the type of activity that's funded.

Travel programs, again, we come into the STAG money situation. $800,000 of this, say, million-three is STAG money, again, to the regions, to the tribes. Then there's about 500,000 left that is administered out of FEAD to support tribal activities of various natures. I believe they have some grant competitions that go out to the tribes and other kinds of support activities.

PBTs, 670,000, persistent biocumulative and toxic substances. There's a little -- well, here it's a relatively small amount. Throughout the Agency, a number of years ago, they identified a pot of money to be use to do sort of address these chemicals or chemicals with this characteristic, and we -- OPP has historically supported about -- that money comes to us as PBT money, and we have historically supported about $500,000 worth for dioxin work at our lab at Bay St. Louis.

Groundwater and endangered species, as we see here, it's a relatively small amount of money. It mostly reflects the fact that a lot of the work is done up here in the negotiating with partners area. So, it looks small there, but in fact, the effort is large and getting larger.

Worker protection, a million and a half, a little over a million and a half. The main activities here are funded through cooperative agreements, and those are basically

assistance agreements that enable EPA to take an active role in the design of the program that's being supported with this assistance funds, and one of the major initiatives that we funded was health care providers initiative, and the other is pesticide safety program for handlers, ag workers and health providers, and so that's the bulk of the million-five spent here.

The certification and training, other, these are, again, funding things such as CAS, which is the Council for Ag Science --

(End tape 4-B.)

MS. MONELL: -- and Materials Force, and then right here we have the certification and training, and this is PSEP, the Pesticide Safety Education Program. This is -- the whole million-two is given to the USDA by way of an interagency agreement to support the county extension service training programs, and this really is the area that you're going to -- we're going to hear about in the next presentation where we are doing a program review, and we have

experienced some difficulty in maintaining levels of funding over the past couple of years, and which I believe we bring in to you for some further discussion and advice.

And I think I've got one more? Yes, I do.

Okay, this is our '05 outlook, and this is basically just sort of for your information. You've read it -- read about it in the paper, probably heard -- you can't see it?

UNIDENTIFIED MALE: Not well, no.

MS. MONELL: Well, it's on your paper. It should be the last --

(Laughter.)

MS. MONELL: All right, well, here we go. All right, for the '05 President budget request, '05 President budget request is $141.9 million, $142 million we requested through the President's budget, and then the three major components of that, reregistration, tolerance reassessment, 60 million; registration, 45 million; field programs, 13 and a half million.

You've heard about the House markup, the House Appropriations Committee had a markup recently, which essentially took $6.1 million out of our reregistration/tolerance reassessment program. That's just at the report stage now. There's been no full action on that. And then the Senate markup takes out $6.4 million from our reregistration program, 2.3 out of our registration program and 2 million out of our field programs. We don't know yet what the final picture is going to be in this area. Needless to say, we're concerned. This is going to be very difficult to continue the progress that we have made in a number of areas.

This figure right here for reregistration actually includes in the '05 President budget a bump-up request. We requested an increment in that particular figure, because as we're coming into the statutory deadlines, we knew we were going to need additional funding, and we thought it appropriate to ask for the extra resources.

At this point, we're still marching ahead. We're still keeping all of our schedules and commitments, and that is our intention, but it's just not going to be made easier by this budget picture.

Anybody have any questions?

MR. JONES: Well, before we open it to questions, I just want to say that we have over the course of the PPDC periodically brought you our budget picture, and I -- it was reminded to me when we had the conversation the last time around PSEP funding just how important it is for all of you to periodically see what the picture looks like. It's hard for you to make informed judgments if you don't have the information that you need, and so, it was a good reminder for me that we need to periodically bring before this committee, this is how we as a program are spending the people's and -- the people's dollars, which includes not just taxpayer dollars but also fee dollars that we collect in this program. So, that was basically what we

wanted to achieve. So, I just wanted to remind folks that we are committed to doing this on a periodic basis. This certainly seems like a logical time to do it given where we are in our current fiscal year.

Caroline?

CAROLINE: Does this appear to be a lack of acknowledgment of what we worked out in PRIA?

MS. MONELL: No. The good news is that neither of these numbers come close to the programmatic budgetary bottom line that we have to maintain under PRIA. In other words, we will be able to continue to collect the fees because both of those provide us with sufficient appropriated funds.

MR. JONES: It might be in spirit but not in law.

MS. MONELL: Right.

MR. JONES: I think Ray was next.

MR. McALLISTER: A couple of questions. Is it my understanding that the figures you're

showing us here on this slide don't include any of the fees that are collected?

MS. MONELL: Correct, only the first slide included a certain amount of fees.

MR. McALLISTER: Okay, the second question deals with the chart on the field programs, contracts and grant funds. I noticed some of the folks around the table furiously trying to scribble in all the names of those programs. I gave up.

Do you have a list perhaps on your web site of -- a concise list of those various projects and programs and grants and contracts?

MR. JONES: No, but we could provide the committee with a further breakdown.

MS. MONELL: Um-hum.

MR. JONES: Allen?

ALLEN: Yes, I -- I'm sorry. In the field programs area this year at $12 and a half million, if I look at your projection for next year, based on the three different groups, if there were a reduction to, let us say, something

in the range of the 11 and a half million down from the 12 million and a half -- am I reading that correctly, that this year there was 12 and a half million for field programs?

MS. MONELL: Correct.

ALLEN: And next year, even though you recommended 13 and a half, it may be as low as 11 and a half if the Senate were to prevail?

MS. MONELL: Correct.

ALLEN: How would that reduction be applied to your chart?

MS. MONELL: Well, that's exactly what our dilemma constantly is, why we're showing this to you, so you would understand and appreciate kind of the tough decision-making activities that we have to go through year-in and year-out.

MR. JONES: Erik Nicholson.

ERIK: Forgive my ignorance on this, but it's helpful I think preceding our next discussion. I'm struck by the amount of money that is allocated for registration and

reregistration and struck by how little is actually allocated to make sure that the provisions and limitations you all put in place through the registration/reregistration process are actually complied with.

So, I mean, in kind of I guess vulgar labor terms, it seems like we're fighting over chump change here. So, I'm just curious, why is that?

MR. JONES: Well, I think that the Agency has historically felt that its primary responsibilities were related to the licensing activities that we're charged with under the statutes, which the fundamental charge. The -- what we do not include in here is the enforcement budget, that is part of the Agency's enforcement budget as it relates to pesticides, and we certainly don't include the programs that are undertaken by the states, whereby under FIFRA the primary -- the (inaudible) for enforcement around use is provided. So, those resources, which are certainly governmental but

are not federal, are not included in what EPA presents as its -- the government resources brought to field oversight, if you may, of the licensing decisions that we make.

MS. MONELL: Erik, if I may, also, these charts only include headquarters appropriated dollars. There is a whole other pot of money that goes to the regions to support our registration and reregistration in the field, and just for the sake of not confusing everybody, I didn't include it in these slides, but -- Doug, do you happen to know off the top of your head what that pot of money is?

DOUG: I don't off (inaudible.)

MS. MONELL: Okay, we can get you that money if -- that amount if you would be interested, but --

ERIK: No, just the one thing I hear constantly from the state agencies is that they don't get enough money to do these inspections. So, it was just telling to see $92-$93 million going for registration and reregistration and,

what, a million and a half to worker protection? It just seems out of whack.

MR. JONES: Amy?

AMY: Well, to follow up on that, I really don't think that you can show that you're protecting -- that you're carrying out a mission if it stops at the -- sort of the front-loaded point. What we've been talking about most of the day today is front-end stuff. When you carry it out to the field and you have people there who are actually implementing the directions on those labels, hopefully they have read them, but if you haven't had the education process ahead of time to help them understand what, why, how, you really aren't carrying it through, and for instance, when you talk about global harmonization, now that's under your registration, right, because that's -- that's not under registration, that's in field operations? We talk about -- I guess I don't know where that is, but that cuts across the whole Agency, and there needs to be a cost of

education built in across the board for actually implementing the things that EPA regulates and tries to have implemented, because the end point, the end use, is if the person out there using the pesticide can't do it correctly, you haven't achieved the goal that we all want to accomplish.

And I also have a question, Marty, about the STAG moneys. Did you say 1.3 million altogether?

MS. MONELL: In the field program, right.

AMY: Well, maybe this includes -- I recognize that doesn't include the --

MS. MONELL: That's headquarters only, headquarters only.

AMY: Headquarters only, okay.

UNIDENTIFIED MALE: Yeah, the STAG money is actually about 13 million all told, and there's another 13 million from OECA.

MS. MONELL: Nineteen. More than that, 19.

UNIDENTIFIED MALE: Nineteen.

AMY: So, I guess that brings up the question, then, if some comes from the regional sources down into the STAG programs, why would that not be appropriate to do for pesticide safety education programs as well if it needs to come from there, if it has to come from somewhere?

MR. JONES: I'm sorry, Amy, ask that question again.

AMY: I guess if you can get it -- if there's some money that goes into STAG from the regions, right, the other half of what the state lead agencies do is -- at least as it comes to CNT and -- well, things that I think of as CNT, but they are not clearly for restricted use pesticide applicators, but GHS education, endangered species education, worker protection education, groundwater protection. Why is there not a possibility of having the money come from the regional programs as well into the Pesticide Safety Education Program if there's a problem

with aggregating those funds?

MR. JONES: The money can -- could move that way. Now, changes in the dollar size is a different question, but how it gets there, that's certainly a possibility. But the amount that's allocated to it I think would involve a much different discussion in the office.

AMY: I guess it's -- perhaps it's just that I'm the only one confused, but if 1.3 million comes it the stags from headquarters and that's the only thing showing in this budget, but there is how much did you say that comes from the regions as well? So, there's a difference in the dollars, I guess.

UNIDENTIFIED FEMALE: I actually think we are going to confuse all of ourselves further. I think we actually should give you a little more precise information about the flow of the STAG funds. If I'm remembering correctly from our Office of Enforcement and Compliance Assistant, it's roughly 19 million total that gets disbursed as STAG funds through our

regional offices that would -- some portion of which would end up with Mary Ellen or Dennis and the other 48 states.

OPPTS provides STAG moneys that are kind of -- I think of it as the complementary program development piece, but it's more in the range of $12-13 million, Marty --

MS. MONELL: Um-hum, um-hum, um-hum.

UNIDENTIFIED FEMALE: -- as STAG money?

MS. MONELL: Correct.

UNIDENTIFIED FEMALE: And it actually never comes or flows through OPP at all. It goes from our assistant administrator's office, Adam's level, out to our regional offices for disbursal to the states again. So, Dennis and Mary Ellen get funding from sort of two sources.

And then there is some additional STAG money that goes directly to the regions, and there's some other STAG money that's in the field program's budget that gets spent, for instance, on some tribal activities.

The total amount is the same, you know,

sort of whatever pot you put it in and however you flow it out to the world, and in fact, I think a lot of that STAG money actually does, one way or the other, get used for various kinds of training and education programs, whether or not they're part of the official PSEP program, but I think it might actually help to sort of see those a little more precisely than this verbal description, how that -- how that works.

MR. JONES: Rebeckah?

REBECKAH: To build on what Ann has said, I think my request was going to be before you're responding is if we can maybe see -- maybe not to the extent of the detail -- thank you, Marty, very much, for presenting the budget this way. I think it's much more user friendly for those of us who don't do this to your level of detail on a regular basis, but maybe if we could get some general information, some general breakdown of the money that goes to the regions and also what may be in OECA's budget that you can attribute to the activities that support

what you do in OPP. I think that would be helpful --

UNIDENTIFIED MALE: We can do that.

REBECKAH: -- both to the folks who are concerned about enforcement and the ones that are concerned about training, you know, just sort of under those general guidelines, what we can attribute in addition to what you do out of the headquarters office, that would be helpful.

MR. JONES: We can do that.

Anything else? Pat?

PAT: Jim, can you give us a feel for the FY '06 submission?

MR. JONES: No.

PAT: I thought it was worth a try.

MR. JONES: Pat, who has worked at EPA for some time, knows that we are prohibited from discussing the budget development --

PAT: Well, I thought you might just in general terms, you know, kind of ballpark it.

MR. JONES: You and the rest of the world will learn in February when the President,

whoever that person is, reveals the budget to the Congress.

MR. JONES: Okay, well, we are going to take a 15-minute break now, and if we could all be back by 25 after, we'll start our next session.

(A brief recess was taken.)

MR. JONES: -- in here.

(Multiple conversations.)

MR. JONES: All right, we -- I'm sure most of you recall, we had a rather lively discussion around our Pesticide Safety Education Program at the last PPDC, and since then -- well, what we committed to at that time, and we are going to follow up -- live up to that commitment this afternoon, was to engage in a program review around the PSEP program, and this afternoon Bill Diamond from OPP's Field and External Affairs Division, the director, is going to walk you there you that, and Burleson Smith, as you all know, from the USDA is also going to make some comments, as USDA has been

very active in this review with us.

So, with that, I'll turn it over to Bill.

MR. DIAMOND: Thanks, Jim. Good afternoon.

Marty started off her remarks by saying that she feels a little like Wonder Woman because she's got the impossible task each year of getting us money and then trying to keep everybody happy. I'll grant you that that's a very hard job, but it's not impossible. What the Red Sox did the last four nights is impossible, and being from Boston, I'm very happy that that's it, but it puts the rest of our work a little bit in perspective. But it also makes the point that the job's not done yet. We have still got the weekend to get going here.

As Jim mentioned, at the last PPDC meeting this spring, there were some concerns expressed about the funding level for the Pesticide Safety Education Program. We

described that we were planning to engage in a comprehensive program review that dealt not with just funding but how it fit overall in terms of the goals and the mission.

What I'm going to try and do here is spend a little time bringing you up to speed on what it is that we did, where we are in that process and where we hope to go in it, and some of the initial comments that we're hearing back from the stakeholders who participated in that process, and then I'll turn it to Burleson to address some of the immediate USDA fiscal management issues that people asked us to talk about, and then we will throw it open for questions, comments or other issues.

If you look at why we're undertaking this, although the funding aspect was the most immediate pressing concern of why we thought it was important to take a look at this program, it wasn't the only one. Just as a matter of good management practice, you ought to be having periodic comprehensive reviews of operations,

procedures, effectiveness and goals. So, we thought it was timely to do that. There's also -- there was a recognition of the changing nature of the work and the demands, and that raised questions about the implications for the national training efforts comprehensively. And then finally, as we all know, there's greater attention to the need for accountability in all of our programs and what the results are buying for the money invested in terms of public funds, and we wanted to see what the implications of that was for this particular program as well.

The goal that we set out for ourselves was to try to assemble a range of practitioner perspectives on a whole range of concerns that would basically be the means to inform our decision-making for what directions or program modifications or changes we ought to make in the future. It wasn't limited just to the funding. If you're looking at funding just in isolation, we don't think you get a high-value discussion. Funding's only important in terms of what the

goals are that you're trying to reach, what you're trying to produce, the vehicles, how you can be as efficient as possible. So, although it's a cornerstone of what we're trying to look at here, we tried to set it in a broader context.

If you look at the basic program purpose here in terms of what the context is broadly, EPA establishes by national standards for certifying applicators for restricted use pesticides. That's administered through state and tribal regulatory agencies.

Effective training is a key means, although not the only means, to ensure that applicators are competent in carrying out their responsibilities there. There's a wide range of training approaches, forms, service providers and sources. Historically, this aspect of the program, the PSEP aspect, has been a critical component of that entire approach.

Laid out there, as we discussed the last time, the ranges of funding that's been

available over the past 30 years. It's gone from a low of 700,000 to a high of 5 million, until just the last couple of years, it had relatively stabilized at 1.88 million. Those funds, as Marty pointed out, are part of OPP's discretionary extramural funds that come to us. They are not an earmark, they are not a set-aside, and they are not STAG fund money.

The assessment process that we went through was to try to maximize the input. We wanted to make sure that everybody was as informed as possible. Again, we weren't looking for any consensus here. We weren't looking for specific recommendations. We saw it more as an exercise to try and identify issues and problems and provide data for us to deliberate on here.

Given that, we thought it should not only have a diverse range of practitioner representatives -- and I say practitioners advisedly here, people who are involved with the intimate details of everything from the operational movement of the grants to the

recipients of the training to the providers of the training and those types of things. So, people who are basically experts and already up on the learning curve here, as a means of gathering the fundamental data.

We distributed to them some fundamental background information to get everybody up on a level playing field. We held two discussion meetings basically to try to identify what the assessment needs areas were that we ought to try and gather some information on, and then together, decide what the critical questions should be that we are trying to ask for input on so that everybody understands what it is and there's not misconceptions in terms of, oh, gees, I thought what you were asking was something else. So, we spent a little time on that.

The product of this would be a compilation of the perspectives, give a little background and history of the program and training and how it fits in the national program

in a report; maybe give a summary of -- for each of the critical questions of the range of perspectives that we've heard; and then attach as the bulk of it the actual input and responses we've got from the participants.

The stakeholder groups that were involved were fairly diverse. You can see the list of the people there. We think they represented the major people that are involved in the -- in receiving the training, providing the training, funding the training. There's a fairly -- we had a good group in terms of experts who did participate, so we appreciate the time that was spent. As you can see from some of the names, it was a fairly opinion natured and outspoken group. We didn't have any shrinking violets. So, we think we had a good exchange of information.

We -- at the two-day sessions, there the discussions I think I could characterize them as both engaged and energized, and I think it put a fine point on some of the issues that

we had so that people could see the different perspectives in some of the areas that we'll be talking about there.

In terms of the time line, since what we are trying to do is not come to a final conclusion or a consensus or any agreed-on recommendations there, we thought a short time frame was appropriate, and I think we've succeeded in that. We started this process right after the last meeting that we had here. We had our first meeting in July. Coming out of that meeting, people requested some additional information on current situations and members and statistics. We tried to provide that to people, although in some of these areas there's a dearth of information in terms of anything from actual members of people trained to some of the definitions of what we mean in terms of some of the potential audiences here.

We had a second meeting to go over that information and basically to refine everybody's understanding of what we were asking for when

they submitted their information. Toward the end of September, we distributed the critical questions. We gave people a fairly short turn-around to answer those things, and we understand that it's short, but given the discussions that we had and how well we think people understood those questions, we think it was appropriate.

We have received input from most of the people, and we will go over that a little bit, some of the initial reactions that we've heard. We'd promised that we would have this update at this meeting, and then the next steps would be to compile the submissions to try and analyze for common threads or themes or where there's real diversity of opinion, put them together in a summary report, and then use that as a piece of information to inform decisions, process changes and priorities in the future.

In terms of the areas that we were looking at, we wanted to throw a broad net, because we think all of these areas are

connected. You can't measure success if you don't have agreement on your missions and goals. It's hard to determine process efficiencies if you're not sure what exactly the priorities are that you're trying to achieve. So, we hopefully thought that there was a thread through these questions that would allow people to give the full range of opinions on the issues that we wanted to express them on and provide whatever supportive data to inform our future deliberations as possible here.

We started at the strategic, the -- what's the program mission in terms of is the mission clearly understood by all critical stakeholders. Hopefully that's a easy part of the questions here, but when you get down to the subquestions in terms of what is the scope of our national training of applicators, what should it be, is it broad enough, is it consistent with the statute, and is it consistent with evolving program needs, it's not as easy as it might be on first blush.

In terms of program activities, you move from the strategic to the tactical in terms of what's actually going on. Is it the appropriate activities to try and meet those long-term needs, however they're defined? And then, how gaps might exist, and then, what should be the different roles of different partners, were all something that we invited comment for under that broad thing.

Program accountability, we set up a separate question for that in terms of what is a good, clear, meaningful measure of success and how do we try and do that without undue burden on people, given the amount of money that's available out there. So, we asked for some ideas on this. This is an area where a lot of people were engaged on. There were not any clear answers but an appreciation that it's an area that we all have to continue to work on.

The other questions got down to program operations in terms of are we being as effective and efficient as possible, are there things that

we can do to improve the management of the funds that we have available, the coordination between the state lead agencies and the training providers, are there other resources that ought to be availed of or are they even possible to do that? So, that's the area where the resources should fit into the larger scheme of things.

Then we asked a catch-all question in terms of the future direction. A lot of times you focus in terms of what you've done wrong or what you want to do looking backwards as opposed to looking ahead. So, we wanted to at least have the perspective looking both ways there, and that's why we framed the question that way. Then we just put in catch-all other question in case there were other comments that people wanted to make that we hadn't hit upon. So, that was the framework that we established for trying to put out the questions there.

As I said, the project is still a work in progress. We haven't received all of the responses yet. We expect them in the -- in a

matter of days. For the ones that we have received, we've just received them, so we haven't compiled them or analyzed them thoroughly yet. That will be a future step.

The next couple of slides, I would like to give you a flavor for some of the initial thoughts of what we heard and also some of the nature of the discussions that we had at the two meetings.

Starting with the first one in terms of the program mission there, we -- after the discussions at the first meeting, we put out a straw man mission statement that you see up on that chart there just as a means to sharpen and focus the comments we're getting in, and that's not to say that everybody agreed on it yet, but the notion of given where we are today at the start of the 21st Century, that the focus of training needs as opposed to just restricted use applicator needs, is fairly broad and very different from when the program started, and get an appreciation of that, and that through a

combination of work of all of us that we ought to try and make sure that we immediate those needs. We have to define rules, have to define responsibilities and funding capacities, but that to help contribute as training should to the overall goal of safe use of pesticides, that was something that ought to be looked at more broadly these days than narrowly.

In terms of the scope of the program -- now, I am not going to go through each one of these things. I think if you look at the thumbnails that we've put here, it will give you a sense of the range of issues we're hearing. You'll obviously have an opportunity to review the report when we assemble it, but I think I'll hit on a couple of these things, because it might inform some ideas of where you'd like to point us in the future if you think that's appropriate.

There was a dichotomy in the initial responses that we've just looked through in terms of what the appropriate range should be.

Some people thinking that the training focus or mission, particularly driven by the Federal Government, ought to be narrower rather than broader, restricted use and up-front certification as opposed to recertification, driven in part by where the expertise is by the recognition of a limitation on funds.

Other people thought that we ought to look more broadly at a range of training activities, not focused necessarily just on restricted use, not focused necessarily even on just general use, but broader ranges of education activities there. And I think you'll see as we go through, this theme kept emerging again in terms of the tension there between what the real responsibilities ought to be.

There was also -- as the last bullet points out there, a sense that there's some tension there between a need for national consistency and direction, so we get focused on some of what we consider collectively as the highest priorities, versus the need for. We are

not all in the same boat here and that there ought to be some flexibility and don't constrain states or others in the field to deal with problems that may be more localized than national.

In terms of the statutory and regulatory things, the consistency with that, again, the answers we've seen so far seem to come at the scope issue, just from a different direction there, the tension between restricted use pesticide applicators versus the notion --

(End tape 5-A.)

MR. DIAMOND: -- the notion that needs have changed, they've evolved, and that they create new demands that ought to be addressed by the training component. We shouldn't narrowly restrict ourselves.

The only point I'll mention on the bottom of this page in terms of the needs was a comment as well that there should be a recognition, not just by EPA but all of us, that the program's evolving, not just because of the

interests in program growth but real different demands than anybody considers historically, and that although those demands are being layered on top of our training providers, that there hasn't been a commensurate increase in funds as we've done that.

As we move from the strategic goals to the program coverage, we asked about current activities and gaps. One of the comments that we heard was who's the audience here? What should the audience be? Should we, again, up-front certification of restricted use applicators or much broader, occupational uses, an area that people thought that training was not what it should be and that there may be, therefore, some gaps in terms of risk protections as a result of that.

In terms of the providers, the question was the -- what's the best mix of providers. There's a recognition that there is no single provider. States provide some. PSEP is obviously a component. Industrial groups

themselves, trade associations, provide training, and questions of if you're looking for efficiencies, shouldn't we all coordinate on clarifying roles and responsibilities, joint development of materials might be altogether some efficiencies for everybody's limited funds, and maybe there ought to be some more done there. And again, I suspect we'll get a range of comments on that issue as well.

In terms of this slide, on the second one here, the only one I'm going to mention and highlight is the mechanisms one. There was a lot of discussion or interest around exploring the potential for emerging mechanisms, where appropriate, not that people aren't already in terms of things like online training or taking advantage of the internet and other new tools. People are experimenting with that, but again, in terms of reaching certain audiences, that that may have some potential for efficiencies there.

Several people did mention a caveat in

terms of you have got to be careful of going down that path of appreciating what your audience is, that not now and probably not for the foreseeable future some of these people are not going to be having that as an avenue that they can access or even that that's the best way to reach these people and to have efficient training, and that explains another I guess tension that we're going to have to deal with together.

The third question of program accountability, this was one that we had some very, very energized discussions on. There was surprising agreement on the general thing. Everybody agrees that there ought to be accountability. It's when you're the one that has to be accountable that we started to diverge a little bit in terms of who should be accountable.

I thought this was an issue focused out to our providers somewhat, but people mentioned that EPA's a little -- ought to be a little

accountable as well. So, we quickly moved on to the next question.

But the notion of accountability I think was something that there wasn't disagreement on. Everybody appreciates that even where there's not a federal funds or state funds or public funds involved here, that when you're reaching people and trying to reach them in a small sliver of time to improve their capacity, that you've got an obligation to do it with value added and accountability in terms of the time constraints you're putting on them as well.

It is difficult when you get down to the specifics in terms of if you're trying to measure accountability nationally in terms of a budget demand from an Office of Management and Budget or the Hill, that's a very, very different, global type of accountability than day-to-day accountability in terms of how effective an individual is in teaching a class, for example, and that's an area where I think

there was probably not as much specificity, although we'll see what the answers are in terms of recommendations, for here are some things that really work, but a commitment that together we ought to do a better job. It's part of our responsibility and it's part of how we should be judging ourselves, much less other people outside.

And the fourth question of program operations and management, the issue was there's often different perspectives on how publicly funded programs can be most efficient and effective. There were comments in terms of the management of the grants, which is one of the things that got us started here, several perspectives in terms of we ought to maintain the current system of EPA/USDA system of funding grants to PSEP, but just try and make it more efficient, to there were comments on the other end that we ought to look at and examine alternative funding mechanisms, perhaps through state lead agencies as well. So, we are going

to have to see the types of information we've got on that, but there is a range of perspectives there.

The notion of coordination between state lead agencies and the providers, whoever they are, is something that people thought was a good thing. People also recognize that there's some areas that people are doing a very, very good job on that, and there's some other people that are not doing quite a good job, and how to bring the people up to the minimal acceptable level was kind of the focus of the discussion, and is it one laggard or is there a bunch of different laggards, and there were different opinions on that, and there's no firm data on it, but I think a recognition that this is something that requires attention. How do you go about that in terms of mandatory grant conditions or just advising or talking to people or something, we're hearing different things.

In terms of the -- as I said, the funding, we didn't want to focus solely on

funding in isolation, but it was an area that we spent a lot of time and had some good discussions on in terms of who should be providing money, who should get the money, what the levels should be. You can see some of the different perspectives up there, and if you do a quick scan, everybody ought to be paying, and I think the last point is that maybe we all ought to try and have partnerships in paying. It's everything from EPA ought to be funding a base amount of money that leverages as it does other people to charging fees, but the fees shouldn't be the sole source, to fully sustainable programs to USDA increasing their funds to associations paying them. So, we heard it all there, and I think it's an appreciation that everybody understands how tough a nut this is going to be to crack there.

In terms of the last one, the future directions, it's, again, kind of -- we hoped to see if there was any common threads and give people an opportunity to give us some

suggestions on that or just their perspectives. It broke out a couple of things, is that there is -- the long term is not very long term if you don't have funds to run your program today. So, we broke it up in terms of you're not going to get to the long term if you don't deal with the short-term problem, but at least you're looking forward.

The bullets under the short-term perspectives that we heard already is that there were some comments that we ought to at least try to stabilize the funding now, at the historical $1.9 million level, so that we could then provide services while we're looking at these longer term issues. Some general comments in terms of some immediate changes you might be able to do, is coordinate programs and materials nationally. There is no reason why people should be recreating them in every different state, get some efficiencies there. Centers of expertise might help in some areas, so there's some hopefully very valuable suggestions there.

And then again, people again brought back to the notion of, well, let's deal with the accountability measures issue in terms of develop them in the near term, not just for ourselves, because if we don't, the outside forces demanding those from us may take the issue away from us in terms of the availability of funding at all. And then the longer term notion of trying and pick some activities to go after, try and address them, but also maybe try and gather a little bit more data in those areas where we're still deficient in those areas.

And then the catch-all one that we heard just to give people an opportunity for anything else they added, we did have a lot of things that we've heard yet, but there was a sense of despite maybe some disagreements on the underlying details of how we run the program or how you move grants or who should be providing it, that there was a uniformity or a universal sense of this is a very, very valuable, important part of the program. That's why it's

been critical for the last number of decades. People don't see that as slacking off with the increasing complexity of the programs and the mission creep, that it is very important, and so it's worth all of us paying some attention and jointly trying to solve the problems there, and I think that's something that we've heard in the general comments, and even for those who didn't give us specific comments, that's the tenor of the discussions, at least when we ended up leading those meetings there.

And you know, correlated to that was that we've got an education issue here and an education issue not just of training certified applicators or others but of educating people who are providing the funds to the value they get from this return, from this investment, and then maybe collectively, we all to try and see how we can convey that to people.

Before we open it up for questions or comments, I am going it turn it over to Burleson now to talk about some of the specific issues

USDA or comments on the general program.

MR. SMITH: Bill, thank you. I also wanted to say that I'm joined by Brad Ryan of the Cooperative State Research Education Extension Service to try to assist with any specific questions, but what I wanted to do very quickly was to follow on to what Bill had said, specifically what USDA's role has been, and if you're looking up at the screen, I don't have slides, so I'll try to be brief.

One of the things that we felt at USDA was that the review of the program certainly was very important. There were issues that we have an opportunity to take a look at and come to a degree of consensus and agreement, but we -- one of the things that we have played a role is because USDA has had a long-standing tradition of working with the land grant universities and have established, you know, a very high level of trust and rapport with those institutions.

One of the things that I would say is that our role has been focused very

predominantly on the funding mechanism in the description that Bill has given, and part of that was that when concerns over funding were raised in 2003, I mean, we've worked with EPA very much as a partner, because we do see this as a partnership in trying to support these activities and to try to answer questions that they had about some of the mechanical processes related to the draw-downs or reimbursements.

One of the things that I would say is that we -- you know, we do participate with EPA in a manner to provide a service really to them and to the land grant universities to transmit these funds that EPA has provided over the last, you know, decades, I think you said. Part of that is because of a unique role that we're able to play in not charging any overhead either at our level or at the universities that are receiving these grants in order to maximize the availability and use of the funding, and this is -- you know, this is something that has been organized, negotiated and is a very special

aspect of this program and this program really alone.

Having said that, that's something that we view this, again, as an area that we have worked very closely with EPA to try to give them assurances that the program is set up in a manner that can meet their objectives as well as questions that they have regarding how the programs are being administered at the state levels.

So, I think one of the issues that Bill has raised is always the issue of measurements or accountability on programs, and one of the things that we have been very keen to do is to avoid a situation where any of the requirements on the cooperators, the actual providers of the Pesticide Safety Education Program, were spending more in terms of resources documenting items than they were actually spending in terms of trying to present the information.

One of the expects to realize is that these are leveraged programs. For the most

part, as Bill indicated, you know, these funds are a fundamental part of the state programs but do not in most cases make up anywhere near the bulk of them. In fact, in one case, in 2002, the funds provided by EPA amounted to roughly 20 percent of their overall training activities. In 2003, that fell to 9 percent, roughly.

So, again, we recognize both at USDA and EPA that these are funds that are contributing to a much larger effort at the state level. We want to work cooperatively in a way that meets the objectives that EPA has in trying to document and have the accountability, and at the same time, provide this unique mechanism that the Department is able to provide with our cooperators at the land grant universities.

So, again, we look forward to, you know, very productive discussions. I think, as Bill indicated, the meetings that I've attend, there have been very few wallflowers or people who have been unwilling to provide opinions and

input on this, and we certainly look to it to -- to the PPDC to provide any insights that you may have.

With that, I think probably it's best to open it up for questions.

MR. DIAMOND: Okay, we just put up here the discussion questions, and we just threw up a couple in terms of given that we're still a work in progress and we don't have final reports together, just give you the opportunity for general questions, general comments, but then also, in terms of what you'd like to hear about in the future, if you've got any ideas in terms of how we should handle this.

Our plans are to, as I said, compile the information, analyze it, put it together in a report. It's not going to be a long or fancy report. It's just going to be, here's what we've heard, so everybody can see the raw materials, and then we are going to sit down with ourselves and with Burleson and hopefully with others and say, okay, where do we go from

here type of thing. Let's pick some priorities, let's -- you know, let's see which ones we can attack, which ones we can't handle, and make some choices there.

If you've got some ideas in terms of how we do that, do we have a general group like we've had, do we narrow it or do we make it kind of project-specific because there's such a range of things. The same type of people who may be interested in trying to have regional development of materials may have no concern at all about the internal, you know, efficiencies or the moving of the grants between us and USDA and others. So, if you have got any questions or comments, we are certainly open to them.

MR. JONES: Erik?

ERIK: Thanks for the presentation. I had two questions. One, what I'm not clear on, is there currently -- are there currently standards, I guess more specifically for EPA minimum standards, that as you look at training need to be complied with to fulfill the

registration and reregistration limitation restrictions you're putting in place?

MR. DIAMOND: For restricted use applicators, we do have minimum requirements, and some of the areas that you looked at in terms of are there resources that we have available at headquarters outside of the PSEP funds that we forward on, to work on exactly areas like that, to establish minimum standard tests, so that people can have common tests across the board that really measure competence and so that people don't have to develop them themselves.

So, in terms of trying to bring up minimal levels of competence, that's an area we're working on. The actual level of what people have to be tested upon is established by the states, and we work in conjunction with them to try to make sure it's as adequate as possible, and as you understand, there's a whole range of different types of uses and other things. So, it's a whole multi-dimensional

requirement there, but we're active in partnership with the states and the others to try and assure that they collectively enhance people's competence.

ERIK: So, I guess a follow-up, as we're looking at I guess, you know, budget reduction to the program, have you all looked at what the impact is going to be on meeting those minimum standards and what that may mean for registrations or reregistrations that the Agency deals with, taking that the -- because it strikes me that the training seems somewhat out here as a satellite, and I'm not seeing a direct connection between the registration/ reregistration work and the pesticide applicator training that this is, in part, funding. So, I'm trying to connect the two and understand in you all's view, how are those related? How are they working backwards and forwards?

MR. DIAMOND: Well, let me take a crack at it, and then some of the other staff here can elaborate on that if need be.

The focus of this was just on the training aspect as you traditionally think of training. As I mentioned, establishing common tests and materials and those types of things were another component that has to mesh seamlessly with that.

Beyond that, in terms of the certification and training program overall, over the last number of years, we've worked in conjunction with a number of stakeholders to try and develop broadly recommendations on what should be done to enhance that program overall. We're starting to implement some of those now. Some of those would involve even things like regulatory changes in terms of our program to maybe expand the scope or put a finer point on those things.

So, we're working on a broad range of those areas underway, and I'm not sure what the implications are yet of the potential budget cuts overall. Clearly some of our budget cuts are not going to help the speed or the quality

of what we do. We are going to have to make some choices there, but until we get, you know, long-term dollar estimates, I can't give you a sense of that. I can give you a sense that this is not the only area that we're working on, and we are trying to do it so it all meshes together.

MR. JONES: I'll elaborate a little bit on that, a couple of examples. When we became more concerned about potential contamination in groundwater, we worked with our state partners to develop a component of the training to bring that groundwater awareness into the certification and training that a certified applicator needed to get.

Similarly, we developed in the last few years a component with USDA and our state lead agencies around fumigants, as we in our old chemicals program began having greater awareness about potential risks associated with fumigants, so that we do link back what we're looking in our licensing operations, both new and old

chemicals, what does that mean about the need for certain components and the training that a certified applicator would have to get.

Again, those are just two examples that I can think of off the top of my head.

MR. DIAMOND: Jose?

JOSE: First, I would like to compliment the group that did this work. I think it's really very nice and looks good and I'm looking forward to whatever final report you are going to put into form, but I don't know that I am going to be saying anything that's really different from what you said, but this money is very, very critical to the states. I know that in Texas we really have suffered, because it's not only the federal but it's also the state. We have had some real significant cuts there. So, the extension service cannot really do the work that needs to be done, and the people are hurting, and they are claiming.

I remember when we first started out with some of the pesticide training programs and

some of the applicator training programs, we had huge success, you know, we could get the people. Now it's getting to be more and more difficult to do it. So, not only do we use this money for seed money, we also use it for leverage.

What I -- I guess this is what Erik was saying, this is not what you had in mind, correct, but there seems to be a disconnect between, you know, we've got registration on one side, and then we've got the training, you know, under a separate program. Is there any way those could be linked together, that the training on the applicator program could be part of the registration? Is that possible? I mean, I don't know -- I don't know what all the components -- I know there's a lot of money in registration to spend, but could that be part of it instead of being separate?

MR. JONES: I think I described how we link it when we learn of things in our licensing all of our new chemicals that we don't feel that the training currently is adequate for, we

attempt to work with other partners to develop a module or a component of the training to recognize that linkage. That's how we have operated that connection between certification and training and licensing.

JOSE: Because I guess what everybody is saying, you go through all the trouble to get all these things raised and do all that, and then you stop short of getting the information out to the people who are going to use this stuff, then how much good have we done? I mean, that's the --

MR. JONES: I think it depends on what your action has been. If you were to remove a product from the market because it had a lot of worker risks, you could argue that that was a whole lot more effective as reducing worker risks than giving someone a brochure about how to reduce that risk or giving them more training. So, I mean, I think that implicit in our funding choices have been how we think you can reduce risk, and we think you can do that

best -- not exclusively, but best -- by evaluating chemicals that have not been evaluated against today's standards and by getting safer products onto the market more expeditiously, but we recognize that there's a need also for this other component that's captured in our field programs.

You know, people can argue -- rational people can argue about the relative priorities, but we have done it in a way that is related to our sense of how you can reduce risk best.

MR. DIAMOND: Amy?

AMY: In answer to the question about the impact and also what is put in, what are the standards, this program -- speaking as a person who's been a pesticide safety education coordinator for more than 25 years in different states, this program has never trained just to the level of the standards, although the standards were set way back then, but it has always been far more comprehensive, and it's not a matter of just giving a couple of training

units, giving a couple of brochures out. It's very comprehensive, and it takes into account different training methods, different teaching methods, different teaching tools that are used.

For instance, I have 132 materials, training materials, that I and my extension agency use to train in my state. Under GHS, I'll have to review all of those and update some of them, and I'll need to begin doing that in 2005 in order to get our applicators to understand what's coming down the road so that when the new labels get out there, they'll be ready. So, I have 132 just in my state to do.

Endangered species is another example of something that was never required, still isn't a requirement, but we do that training. It fits. We do it. Why would we not do it? Our growers need to understand that.

In other programs, it's not just growers. It's people like structural pest control operators; it's people like health care -- public health folks who need to know all

of this extra stuff, much of which does come straight from EPA, and we monitor that and take it and put it into our programs whether it's required or not, and certainly we haven't gotten extra money to do that.

As far as the impacts, well, again, I've told you about what I'll have to do to review the materials, but also, states are already losing personnel. California had a very big program with excellent outreach not only to applicators but also to health care providers, and their personnel have all found other jobs as of September 30th of this year. In my state, I'm being re-assigned to teaching duties, because the extension dean does not have the money to pay the $8,000 that's missing in my salary.

So, there are real impacts occurring now, and if we wait until the long term to shore up this money, these programs will be lost in the interim, and you won't be able to fix them.

MR. DIAMOND: Allen?

ALLEN: This may be a nearly impossible task, but I would encourage the Agency to think of the overall mission of the Agency and protecting health as one of the measures that might be applicable to assessing the impact of training. The reason, of course, that I'm saying that it's difficult is that it would be very difficult to segregate an effect that's due to training from changes in regulations, introduction of IPM and so on and so forth into the way pesticides are used, but nevertheless, I would encourage the Agency as it thinks about how to assess accountability to include some kind of thought about health outcomes in the final measure.

MR. DIAMOND: Not just for this program but for a whole range of programs, we are looking at accountability instruments at the strategic level and then throughout the program, and obviously health incidence or reduced health impacts is where people start from in terms of the ideal outcome that you'd like. There are a

lot of challenges there, as you all know, in terms of compounding variables, tracking types of things.

So, we're looking at that or we will be looking at that for this and for other programs, but also some interim or some not quite, you know, top-level outcome measures. If you can measure changes in behavior, if you can measure increased applicator competence, we don't think it's a large leap between there and reducing the health effects. So, we're going to try to be exploring a whole range of those that give us some meaningful information but are not unduly burdensome in terms of trying to track and collect that information.

ALLEN: Given the costs of today's health care and the size of your budget, you don't have to prevent very many hospitalizations or chronic illnesses before you have recouped -- more than recouped the cost of training programs.

MR. DIAMOND: Oh, I think you're

preaching to the choir here. The leap in terms of demonstrating and documenting that so that a hard-eyed analyst can say that it's a good assessment is the challenge we face.

Rebeckah?

REBECKAH: I'm going to try to be helpful in being a participant in the group and maybe say some things that because of EPA's obligation to remain objective and deal with the budget it's given, just bring a little bit of a sense of the reality from somebody who's participated in the process, participates in helping advise the appropriations process legislatively and also represents a very substantial portion of the end users of this these programs.

I just want to let you all know that a lot of the conversations and the points that you've raised were conversations and points -- very extended conversations and points that occurred over the course of the four or five days and the ongoing discussions that the group

had and will continue to have, and it was a very steep learning curve for a lot of us to see not just how the program worked from the federal level and the dollar flow-through, but also how the different state programs and extension viewed the different programs and the variety.

I guess the hopeful part is that, as Amy said, almost without exclusion, the folks that were there either representing academia or state programs of some sort almost always said, you know, this is what leverages us. This is sort of the big -- the important grounding piece of what we do, but we pull from so many other different places to get money, either at the state or federal level, and we go over and above based on the state needs of the people that we're trying to train, and you know, we take EPA's requirements and guidance and money as our baseline, and then we build into that.

So, you know, what people are getting is a lot more than just what EPA's asking for. That's the good news. The problem is with --

you know, lean and -- you know, thinking of 50 states doing programs, and if you divide that money up among those people and you think of all the training programs that you would need and all the staff people it would take and all the time it would take, even in a small state, to, you know, educate hundreds or thousands of people, depending on the circumstance, you know, you think of 1.88 million, and for this coming year, we're looking at 1.2 million divided among 50 states, is certainly a lean and mean program, to say the least, and we're very concerned I know from our perspective of making sure that EPA has the money to get that flow-through out there. Probably in our minds they need a lot more, to do a lot more and to allow a lot more leveraging.

That being said, we are having a challenge, and it's a challenge that Bill has, and you know, theoretically, behind the scenes, I suspect EPA asks for a lot more, and they like to have more money and more dollars to give to

people to do these programs. Realistically, when they send programs for evaluation through the OMB process, through the appropriations process, both through an administration and through Congress, performance measures matter in tight budget years, and the problem and the challenge that we've come to discover that EPA has in justifying not taking a haircut or getting more is providing that performance-based information of what we're getting for our money, even if it's just a tiny piece.

You know, the Office of Pesticide Programs doesn't in the greater scheme of EPA's budget get a whole lot, and they certainly in the greater scheme of the federal budget don't get a whole lot. So, you know, they're being nickeled and dimed to death, literally, and unfortunately, this is one of those programs that without being overburdensome to the providers, the folks out in the states that we want to be using their time and money and preparing and giving the training, not in

filing, you know, endless paperwork for EPA to be able to show to OMB to go, "Oh, here, look."

You know, we just don't want statistics on paper. We want people trained. We want them gaining knowledge on doing the right thing. But there's a very fine line between getting EPA their justification and keeping these programs and not being overburdened with the paperwork, and we've found -- you know, those of us participating have found out that is the big struggle, is more so than EPA thinking it's a valuable program or even the states certainly thinking it's a valuable program and the providers or the users thinking it's a valuable program, is trying to figure out the best mode in the long term to figure out how to show the rest of the Government, both Legislative and Executive Branch, in whatever year in whatever cycle, how important proper application education is, and that has been -- that's probably the most enlightening light bulb notion that has occurred for all of us, and in the

meantime, in the short term, making sure that what we do have stays in place and doesn't get further haircuts until we can figure out, you know, how to give OMB and these other folks what they need, and I think --

(End tape 5-B.)

REBECKAH: -- and their relationship with another agency and with the appropriators on the Hill. So, from an outside perspective, I think that's a very key lesson that I would like everybody in the room to know, that that is our fine balance of trying to perform and get more money to do the right thing.

MR. JONES: Well, I think that one thing that is perfectly acceptable and encouraged for us to be saying and doing is what you're saying about results, that results do matter, and being able to demonstrate results is very important in the Executive Branch, has been for a few years, but we are seeing more and more --

REBECKAH: More and more.

MR. JONES: -- the pressure to be able to demonstrate results, and it doesn't mean counting number of people trained or number of licenses granted, but on the ground, in the field, how did it change risk to the environment or human health. That's very important, and the better we're able to do it, the better we're going to do.

UNIDENTIFIED MALE: I'd like to bring up just one question, and it's from some information that Amy brought up, but the question is really to you, Rebeckah.

Basically from the reduction or loss of funding in California resulting in losses of positions, apparently, I mean, is that in your mind a performance measure? I mean, you don't normally go in and seek to do something like that, but --

REBECKAH: I think that certainly from the perspective I'm assuming of the providers and from the perspective certainly of the people who are needing the service, especially those in

the private application community where they're not necessarily part of the community, sometimes -- there are certain industry sectors, commercial applicators, do some of their own internal programs, but certainly private applicators, the individual farmers, folks like that that aren't considered commercial, rely very heavily on these programs, and those are a lot of the people that I work for.

The notion that there are programs there that are either declining in their training availability or in the personnel to -- or in the program completely or in the people who are able to provide the programs is exactly the worst case scenario. It's exactly why, you know, less than adequate funding, even in tight budget years -- there are just some things that you don't -- that you -- that can't go away.

There's a critical mass of funding for certain types of very important programs, whether it's, you know, training, general worker protection, some of these other things, we're

seeing, you know, some might notice, the hold field service's budget was substantially smaller, not because registration and reregistration aren't equally important.

We want everybody to get the right amount of money they need to perform the function that they need at EPA, and I think we all know that, you know, right now, the field services group is not, and that is going to be a huge -- you're probably going to be seeing some correspondence, not necessarily focused on EPA -- EPA's recognition that that funding is inadequate and needs to be increased in order to get back these programs before they're gone forever, but you're probably going to see it happen at other much I guess -- I don't want to say higher levels, but certainly at different levels to understand that until we refine the performance measures to tell you what you need, appropriations committees or OMB, we're losing programs, and if that's not a performance standard for you, if that's not an indication of

the critical need of a program, that, you know, in the meantime -- give us a year or two, and in the meantime, when the field services program in OPP says we need this for this program, give it to them, and that is going to happen, is happening.

MR. DIAMOND: Okay, thank you. We will just take a couple more questions and then we will move on to the next session.

Ray?

RAY: I have got several points and questions. I hope I can make them quickly here.

I've heard there was a misunderstanding between EPA and USDA on how the PSEP funds were accounted for and that this misunderstanding has contributed to the funding crisis. Has that been resolved?

MR. SMITH: Yes, let me just say that the -- part of the issue was a matter of timing. It's a little bit like watching checks clear the checking account, and I think for the most part, we've come to the point where we agree that

what's in the check register and what's on the statement are in agreement now.

The issue that I mentioned to you in terms of looking at ways to simplify the process was to speed up this activity, but also part of it is a matter of cooperating with the state institutions in terms of their billing practices. It's amazing when moneys dry up how quickly people will start to tap in and ask for reimbursement for everything.

So, as far as I'm aware, through 2002, everything has pretty well been cleared. It's 2003-2004, the more current funds, that we are dealing with right now.

MR. DIAMOND: Yeah, the -- that issue was one of the initial issues that confronted us in 2003. I think the backlog, as Burleson said, has been cleared up. The issues in terms of some of the other administrative aspects of how we handle grants, documentation for what's actually being -- the material's being spent on, those are issues that have been identified. We

are still working to try and resolve those, but we think we've got a path ahead of us that will straighten those out so that we can deal not with the day-to-day nuts and bolts handling of the dollars, which is important to get it into the hands of people in a timely manner, but the more institutional and strategic issues. That's what our hope is.

Allen -- oh, excuse me, Ray, did you --

RAY: I have got some more here.

When the Agency establishes priorities for funding among the various projects under the field programs umbrella, what level of accountability are you requiring of the other projects?

MR. DIAMOND: As I said, when we're looking at accountability, we're looking at accountability across the board in terms of what the heck is going on, and in all of the programs that I'm responsibility -- that I'm responsible for, we're looking for each team, each branch, in terms of what measures of success are we

going to be held to. So, we're looking at that from outside drivers.

Just one aspect of it is in terms of the OMB performance assessment review tool that's going on. We have had that for each of our grant programs this past year. We haven't got our evaluation yet, but for ESA, for water quality, for certification and training, for worker protection, one of the fundamental questions is, what's your performance accountability measure, what's your documentation, and how good is it? So, there's a microscope on that.

We're preparing for that in other areas, but even areas that will never get that type of review, we are looking at that, and I think that's just my program, but I know it's across the board in OPP. Jim's launched over the last year or two an office-wide effort in terms of trying to improve our measures.

We've got a meeting next week where we're discussing that exact same issue with our

regional partners so that we're all in line on these types of things. So, this is not just the only program that that question's being asked at.

RAY: In the budget figures that Marty showed us a little -- a short while ago, there was -- the Senate markup had a $1.9 million reduction in the field programs compared to the President's request. Is the similarity of that amount and the historical funding level for PSEP more than coincidental?

UNIDENTIFIED MALE: Coincidental, I expect.

UNIDENTIFIED FEMALE: It's totally coincidental.

RAY: Okay.

UNIDENTIFIED FEMALE: Yeah, it should be.

RAY: Well, in the mid-1990s, we saw a partial dismantling of the pesticide data program caused by a similar funding crisis, which threatened the existence of that very

valuable program. Fortunately, funding for that program was subsequently stabilized. I'd say that PSEP is at least on a par with PDP in terms of risk reduction and long-term public health and safety, and it deserves a similar rescue, if that's the word for it.

At CLA, we would strongly support restoring the funding for PSEP and would hope that that stability in the long term can be rapidly achieved. Of the total volume of the pesticide market within the U.S., the proportion physically handled by the applicators who are served by PSEP is vastly disproportionate to the funding provided for this program, and the leverage we've heard about, you know, kind of the matching funding that you hear about on public radio funding drives, you know, that's what makes the training programs work, is the leverage that can be provided by EPA, and we hope it can be stabilized.

MR. DIAMOND: We hope we don't have to be a call-in yet, but if that's what it takes, I

guess maybe we'll explore that as well.

Jim, how much more time do we have? We have got three or four more questions. Should we just keep going?

MR. JONES: We'll take the three that are up and then move on.

MR. DIAMOND: Okay, Allen.

ALLEN: Mine will be pretty brief.

Does anyone from the Agency or the states know how much commercial training is happening, in other words, training for profit by individuals, and is that an avenue that has been explored as a way of offsetting reductions for agencies to do training? I know some of it goes on. I just wonder how much goes on.

MR. DIAMOND: We did discuss that in terms of -- as one of the potential gap-fillers or some other things. Nobody came up with good, solid information. There was some anecdotal, and we asked people to provide some additional information.

There were some figures that were

tossed around in terms of burden on the individual in terms of getting the public sector ones, even where they charge fees, being much reduced from the private sector ones that may be more expensive, and therefore, limiting access. So, there's a tension that's involved there, but we -- when we asked the question, we didn't come up with any answers in terms of here's the whole, overall perspective, and that's where we started, you know, having some issues of just the information dearth to be able to to try and address these questions.

Before I move to these, Amy, did you have something on that?

AMY: Just two quick things. There certainly are other providers of this kind of education out there, and they do a very good job, but part of the reason why many of them do a good job is because they have extension people on their programs contributing to it. So, again, you won't have that link if the extension program goes down the drain.

The second part is you have to be careful that -- you might have been addressing this, but when private individuals come in, they're going to -- they can do it for agriculture, for structural pest control, for some of our other large -- for landscape and ornamentals, but for the right of way, the aquatic, the tribal tin boat bottom painting, which I guess won't last much longer, the fumigation, the wood treatments, all of those little categories, they're not going to step in and do that training.

MR. JONES: This may not be directly responsive but I think in the spirit it is, Allen, but my understanding is some states also have some kind of a fee for the people being trained, so that you're --

UNIDENTIFIED FEMALE: Absolutely.

MR. JONES: -- but not all of them do.

UNIDENTIFIED MALE: And they should.

ALLEN: I think it is an avenue that should be developed more so than it is. I have

some personal experience. A very highly qualified individual does do commercial training for profit and has, in fact, run into quite a bit of resistance from some states as he's tried to expand into additional states, and I'm not being critical. I just know that he had that difficulty as he wanted to move into other states, those states being resistant to individuals, even highly qualified, offering that for profit.

MR. JONES: I am just going to take two more, Rick, if you could just sort of --

AMY: I would just like from a production/agriculture/private applicator perspective, because we are significant users of the public -- more public programs, I think that there is a lot more availability, a lot more privatization and a lot more commercial application for folks like your members, who are structural, who are whatever, and I think that's something -- nobody wants to discourage that.

Probably the resistance that was sensed

is depending on the pool of people seeking training, if it reaches such a low level that no commercial people in some circumstances, in some states, are coming through that program, and it's only a sprinkling of the private applicators that are out there perhaps in smaller states, then the ability of the program to operate for -- cost effectively for the out-liars, the private applicators and whatnot that perhaps couldn't afford the usually a little bit more expensive, at least, commercial programs, becomes an issue.

So, there's that sort of tension there, that we don't want to discourage people certainly from providing the private training, but realize that there are people in the system who really need that subsidized training, and when you sort of erode away that base, it creates a pressure there for them.

MR. DIAMOND: Mary Ellen?

MARY ELLEN: I just wanted to state the obvious, that accountability is absolutely

necessary, but in order to do it, it takes resources. The Chesapeake Bay Program for years funding integrated pest management programs, and there was a call for accountability to show that those programs were making an impact, and the states did that, but it was a very extensive and long, drawn-out process to gather that information and put it into a program or explanation to show that some impact was being made, and without resources, you're not going to get that either.

MR. DIAMOND: No, and that's one of the things that makes it so difficult. As I said, everybody appreciates that accountability is valuable and important. Accountability in some people's eyes means a lot of paperwork and documentation. In other areas, it's -- even if it's not heavy-duty just paperwork but has value, as you indicate, it's very expensive to get good data, and you have got some people who are asking for accountability information who want every last range.

I think hopefully we'll strike a reasonable balance that we get better than what we've got now but don't go overboard, and some of the ideas that were just kicked around initially were, can you do instead of having everybody, every year provide information on outcomes, can you do snapshots? Every three or four years, go in, do an intense evaluation in terms of maybe changes in behavior and see trends over time? That's less intense, doesn't require everybody to do it, but may give you some valuable information.

That may not be up to snuff with what some auditors may want, but it sure could help make a case in terms of here's what the real value is, here's some documentation, and now let's go back to our core business of providing that value.

UNIDENTIFIED MALE: But is that something that as the program manager EPA would be willing to consider or is that something to require each of the grant recipients?

MR. JONES: We've been very flexible in our willingness to consider various measures and results. It's those who are overseeing the part review that isn't accommodating to some of our creative thinking.

All right, Burleson and Bill, thanks very much, and thank you all in the PPDC for all that advice and feedback.

The last part of our program, before we get into it, I just want to mention for members of the public, if there is anyone who would like to make a public comment -- so far there haven't been any sign up -- but if you would like to, Margie Fehrenbach, you just need to let her know, and we will do that after this following session here, which is our last session this afternoon.

I believe Lois Rossi, Debbie Edwards, are going to walk us through some basic -- some of our accountability to you around our registration and our reregistration programs, and also, the last topic that Debbie's going to

cover is the future as it relates to a class of compounds in our old chemicals program that is of significant -- of significance to I think a number of you that we wanted to give you a sense as to where we are and what our schedule is going forward on fumigants.

I think Debbie, you were going to -- or Lois, you were going to start. Is that right?

MS. ROSSI: Yeah, I'm just going to briefly run through the program priorities and -- or program accomplishments in the registration area for 2004.

As you can see from the slide -- and I'm not going to read through -- don't worry, I'm not going to read through all the names of these chemicals -- our program goal was to register 26 new AIs, and the breakdown was 12 conventional, 12 biopesticides and two antimicrobials, and in meeting that goal, 14 biopesticides were registered, and they are present there had for your information on the handout, and then on the next slide, 11

conventional pesticides, with one noted for import tolerances only.

I would like to point out on this, though, the breakdown, of there -- there -- among these pesticides, there were five reduced-risk pesticides registered. One of the reduced risk was also an OP alternative, and there was one methyl bromide alternative registered. Antimicrobials had two new active ingredients that they registered this year.

And the other major activity is with new uses across all three programs or all three divisions. A total of 718 new uses were registered, with the breakdown of 231 conventional new uses associated with 1008 crops; 481 biopesticide new uses; and six new antimicrobial uses.

Those are the two categories that certainly get a lot of attention, but this year I think we've also had a new one that's pretty much had a very low number or maybe even in some years in the past no number, but in the inerts.

We did register food -- 16 new food use inerts this year and three polymer exemptions and 83 nonfood use clearances. So, this is -- our goal for the food use inerts was 12 this year, and so we made it to 16 and reduced the backlog considerably. The backlog now is at 38, and that consists of four additional applications we got just this year.

Also, a lot of the registration activity is with fast tracks and non-fast track amendments and new products, and you can see the numbers there represent a sizeable amount of work with the fast-track amounts, non-fast-track amounts, fast-track new products, non-fast-track new products and our notifications under PR Notice 98-10, and that's RD, and then following, RBPPD, with the same categories, and the numbers are presented on your handout, as well as AD, the numbers are presented on your handout.

And then last is the Section 18 activity. We received 345 requests for the program this year, approved 238, 20 were

withdrawn, four were denied, and in 27 cases, crises were declared, and our average turn-around time this year was 38 days.

We also, on the bottom, we also have been working very closely with USDA on granting Section 18s in the event that soybean rust arrives from South America. So, we've also had considerable work in cooperation with USDA on that activity.

And that, in brief, gives you what our registration accomplishments were this year.

MR. JONES: Rebeckah, I assume your card is up from the last discussion?

REBECKAH: Oh, yes, excuse me.

MR. JONES: All right, thanks.

Debbie -- oh, I'm sorry, Gary?

GARY: Well, it was just a fast question. What does that mean, "crisis declared," on your Section 18s?

MS. ROSSI: That means when you don't register the 18 in enough time and there's the emergency that's there, the state has the right

to go crisis. That's my elementary understanding. You past directors can back it up with more explanation, but that's basically what it is, where we are not able to grant the 18 and the emergency there. I'm sure a state person can elaborate, too.

UNIDENTIFIED MALE: That's it. Help me out here.

UNIDENTIFIED MALE: Yes, that's basically correct. The states have the authority to declare a crisis when they need a pesticide that's not registered for the use and when it's going to take the Agency more time than is feasible for the evaluation of the need, and what happens usually is -- well, typically, the crisis is declared, the pesticide is used, there's some consultation with the Agency when that's being done, and after the crisis is declared, a specific exemption is prepared for the Agency to review it.

MR. JONES: Gary?

GARY: Lois, I'm just wondering, is the

trend on the Section 18s, is that continuing to go down?

MS. ROSSI: Well, I think as we register more new uses and particularly if we start addressing, as we are this year, a lot of the IR-4 uses, it should go down. I mean, we're definitely looking at that, to see how many 18s will go down if we register a new use. So, I'm sure a lot of the 18s are associated with new uses that have been pending for a while, because they didn't make the work plan, and now, under PRIA, where our work plan is going to be totally different, I'm sure you'll see that -- I'm sure you'll see a downward trend.

MR. JONES: Shawny?

SHAWNY: I'm wondering, I know there's a new PR Notice out on Section 18s open for public comment right now, and the stated goal or objective is to streamline the Section 18 process, and I'm just wondering -- well action I'm probably wondering many things about the whole thing, but if you're showing that 38 days

is the average to get these applications through and approved and the goal I thought was around 50, why does the process need to be streamlined?

MS. ROSSI: Well, it's 38 days, but that's an average. So, there's -- I mean, it's not a median. I mean, it means that there's probably some highs and some fast turn-around times, but I think --

SHAWNY: That's a pretty good average, though.

MS. ROSSI: Yeah, but it's still --

UNIDENTIFIED MALE: Thank you.

MS. ROSSI: Yeah, thanks.

MR. JONES: I'll take a look --

MS. ROSSI: Yeah.

MR. JONES: Part of the streamline is around paperwork burden for the states associated with those 345 requests. Actually, a large part of it is around that. I do want to say that we're in the comment period now, and although, Shawny, this is your first meeting, we've probably had two hour-long discussions

around that proposal before we put it out at this meeting, and I will -- there was never full consensus around either of the options, but we are in the proposal stage right now, so I don't want to get too much into what the -- implying what the Agency is ultimately going to do until we have reviewed all of the comments on that.

All right, thank you. Debbie? Debbie Edwards, by the way, in case you don't know. I'm sort of casually referring -- and Lois Rossi, the director of the Registration Division, for those of you who may not know her, and Debbie Edwards, the director of the Special Review and Reregistration Division. Sorry for my informality.

MS. EDWARDS: That's fine.

I'll go through this pretty quickly. I think I have a lot of graphs here and so forth that are pretty self-explanatory, but last year we did complete -- the program as a whole, that includes biopesticides and antimicrobials, as well as conventionals, 35 registration

eligibility decisions, 17 of which were REDs and 18 are TREDs. TREDs are just where you look at the tolerance reassessments as opposed to the entire picture for the chemical, and that -- which includes worker risks and ecological risks and so forth. We also did 25 inert tolerance reassessments, and we did -- we did 25 inert tolerance reassessments for a total of 467 tolerances reassessed last year.

These next two slides I want -- you should have them in your package. They are just a listing of actions completed. If you look at the actions that were done -- this includes inerts and just every -- pretty much everything we did in the old chemicals program. You'll notice that a lot of these are what you might call low-hanging fruit, I guess. We felt that they were lower risk chemicals, and we're trying to get as much done as we can now on the easier ones so that we have all the time we need to work on the harder ones that are coming up in the next couple of years, although some of these

weren't particularly easy, I might say.

The next slide is -- this is a slide we always show here. It's the overall status of tolerance reassessment, and our RED completions -- you can see we have 244 REDs completed with 138 left to complete, and that part there in the middle is the 231 cases that were actually cancelled, so...

Then on the right there, you have our total goal for tolerances overall by 2006, 9721, of which we have reassessed over 7000 at this point.

This shows our reassessment progress by year. You can see there that this year we did the 467. Look back, you'll see that in 2002, we actually did 2657. That's quite an achievement that year, but I would like to point out that in 2005 and 2006, we -- if you subtract the ones that were already done from IREDs, we only have around a thousand to complete each year, so I think it's very doable. You'd just be up to that second line on the graph there for 2005 and

2006, and we would be successful and done basically.

The next slide is just the cumulative. It's another way of looking at what we've already presented, just a bar graph there.

The next slide shows where we are in our cumulative assessments. As you know, we're working toward four cumulative reassessments for the organophosphate pesticides or insecticides. We have three individual chemicals to complete, and we're planning to complete them in this fiscal year. That's malathion, DDVP and dimethoate, and we would then hopefully complete the OP cumulative by the end of this coming calendar year.

The chloracetalanilides, which are acetochlor and alachlor, are again scheduled to be completed in 2006. We expect that to be a relatively simple cumulative assessment. There's little or no exposure from food, and there may be some co-occurrences in water, but that's all we would have to look at there.

The M-methyl carbonates, obviously there's quite a bit of work to go there. We are going to have a couple of SAPs coming up this year, and our goal is to complete them more around the middle I think of FY 2006.

And then finally, the triazines, cimazene, atriazine and propozine, again, I think that's probably going to be a little bit more difficult than the chloracetalanilides, put nowhere near the difficulty of the OPs and methyl carbonates.

Right now, we are at for -- as we complete chemicals, we call them interim REDs. We call the tolerances that we reassess there uncountable at that point until we complete the entire cumulative assessment, and right now we're at 548 tolerances associated with those interim REDs that we're not actually counting as reassessed, although we have completed the actions on the individual chemicals.

And this just shows you what I'm talking about there, the sort of greenish part

are the uncountable tolerances as they're accumulating. So, in total there, that bar next to the end for 2004 actually takes you to 7641, and that's why I said earlier, we in reality only have about 2000 left to go.

The next slide, these are the tolerances remaining to be reassessed, like I said, including the -- if you look there at the bottom, that number, 2628, includes the 548 which we are currently -- have completed, but called them uncountable at this point. There's 447 inerts and 60 antimicrobials tolerances, only two biopesticide left, with most of the remaining being the conventional pesticides.

For 2005, fiscal year, our goal has us doing 47 reregistration eligibility decisions. That's 31 REDs, three interim REDs, and that's for malathion, DDVP and dimethoate, 13 TREDs. We would do a total of -- these numbers are presented a little bit oddly, but there's 122 inert tolerance reassessments on the goals sheet for this year, 745 tolerances that would be

counted as reassessed, that includes the inerts, and then an additional, over and above the 745, 207 that would be uncountable associated with those IREDs that we're planning to do.

Some of the highlights of the work we'll be completing this year are 2(4)(D) and chlorosulfuron, both herbicides. Also, the EBDCs, fungicides that are -- I'm sure you're all familiar with those, PCNB, and then again, I've mentioned before, these are the IREDs we have planned, malathion, DDVP and dimethoate, among other chemicals. These are all posted on our web site.

You can see her the first web site will give you the full schedule for reregistration through 2008. We're actually going to update that by the end of this month. The plan is to update that probably at the beginning of every fiscal year. And then the second web site there is our public participation schedule, which is a six-month schedule that we update every three months. So, it's kind of a rolling schedule.

We keep six months ahead of us. It never goes down below three, because we update it every three months.

So, that's it for reregistration.

MR. JONES: We can take any questions on that before we move on to the last topic.

(End tape 6-A.)

MR. JONES: Erik?

ERIK: Do the budget cuts that we heard about, are they going to affect your ability to meet the deadlines?

MS. EDWARDS: I can't say for sure right now, but I am -- I think we're in actually very good shape with reregistration. Naturally there's a lot of heavy-duty work ahead of us, but our goal is still to complete it, and until we actually get the budget cuts and analyze how that would -- how it would affect us, I'm not -- I don't know, Jim, if you want to say anything on that.

MR. JONES: We have made some estimates internally that we are forwarding on to the

chief financial officer, who then sort of is forwarding them on to the appropriators. We do think that it would impact our ability to deliver the number of REDs and IREDs that Debbie discussed both in '05 and in '06. That's our current projection. I mean, if it does happen, as program managers, we will do everything that we can to try to minimize the likelihood of that happening, but we do think it would impact our ability to ultimately achieve the deadline.

MS. EDWARDS: Right, yeah. I mean, right now we're operating assuming we'll have the money, and so that's our plan. Our plans going forward do include having the money.

MR. JONES: Shawny?

SHAWNY: I'm just wondering if you have this presentation, if it's outside in a handout form.

MS. EDWARDS: Yeah, it should be.

MR. JONES: It's in the packet.

MS. EDWARDS: It should be.

SHAWNY: It's in the folder? Okay, I

just couldn't find it. Not surprising.

MR. JONES: Carol?

CAROLINE: Yeah, I was just wondering if you were able to be specific in your analysis of how it would impact you and if you would share that.

MR. JONES: I will have to check with the chief financial officer about sharing it, but the degree of specificity is in number of REDs and IREDs as opposed to naming them.

CAROLINE: Right.

MR. JONES: Um-hum. We have done -- we have identified how many. Again, I'll need to check with the chief financial officer before I share anything --

CAROLINE: So, if you would like us to talk to the Hill about it, we would probably need that information.

MR. JONES: I wouldn't encourage anyone to talk to anyone about anything. I'm just telling you what I know.

Erik?

ERIK: I'd just like to say I'd welcome the day when we can have this degree of specificity from the WPS implementation and compliance side, to see specifically what's going on out there. This is really interesting on the registration side. It would be helpful to have it on the tail end as well.

MR. JONES: Okay.

All right, with that, the last presentation is also from Debbie.

MS. EDWARDS: Okay, the soil fumigants. Many of you hopefully have heard by now we're doing an assessment of all the soil fumigants together. What I'm going to talk to you a little bit about today is the scope of that assessment, a little bit about what our objectives are and why we're doing it this way, what some of the challenges are that we're facing that we hope the stakeholder community can help us with, and something about our schedule and the public process we intend to follow.

In terms of scope, we're actually doing -- what we're talking about here are human health risk assessments for six soil fumigants. These include iodomethane, which is actually not registered yet, that's a new chemical that we're assessing, Telone or 1,3-dichloropropene, which actually had a reregistration eligibility decision completed in 1998, but we felt it made sense to look at them -- if we were going to look at them all together, we didn't want to leave one chemical out. We felt that would do a disservice to the public and probably be confusing.

Then the other four are still in the reregistration mix, actually. There's methyl bromide, which is actually -- it's a food use chemical in that it has tolerances established. All of these would be used or are used on food crops, but they don't all have tolerances, andiodomethane doesn't look like it would need tolerances, but methyl bromide has tolerances, and that's mainly for post-harvest uses. It's

used as a fumigant for commodity treatments.

Then there's chloropicrin, which is often used in combination with the other chemicals, and then metam sodium and dazomet, which are MITC generators. They have some similarities in terms of how they actually work.

UNIDENTIFIED FEMALE: What are MITC generators?

MS. EDWARDS: Methyl ice sew sigh nature.

Okay, our objectives, and this probably mostly has to do with why we're doing these concurrently. I will say that there's been -- there had been a history in the program some time ago, which Al Jennings is certainly familiar with, of the Agency feeling that it might make the most sense in terms of risk trade-offs and benefits and so forth to look at chemicals, all the chemicals that would be used on a given crop, to control a given pest, at the same time, and that would allow us to make more informed decisions. We found that in most

cases, that's not been practical, but in this case, we actually believe it is practical, and so that's one of the reasons we like to do it.

Our objectives, then, as we go into this ensuring that we are aware that soil fumigants are very essential to agriculture, some of the most important chemicals used in certain -- on certain crops for certain pest control tools, and we want to make sure they're both available but safe -- and safe. We want to make sure that we have a level playing field by evaluating the alternatives concurrently and consistently to the extent that that's possible, and I'll talk about that a little bit more in a minute. And also to ensure that our risk management decisions don't result -- again, like I was mentioning before, in risk and benefit trade-offs that don't improve safety and do not help agriculture either. What I'm talking about here is as we make informed choices, we want to make informed choices such that any regulatory action we take will be able to predict what the

downstream effects are.

In other words, what will -- what -- if we made this regulatory choice, what would the grower move to next, and what would be the risks there, if you get my drift? I think it's pretty obvious, but anyway.

In terms of the challenges we're facing here, and this kind of goes back to doing this as consistently as we can with the data we have available, for some of these chemicals, we have pretty good monitoring data. For others, we don't. We're faced with using modeling. I don't think we probably have sufficient monitoring data for any of them to base an entire risk assessment on it, but certainly monitoring data, air monitoring data, is always very helpful. And for those of you who aren't real familiar with soil fumigants, the reason bystander exposure is such a big deal for these and the reason we're focusing in on it so much is fumigants by their very nature, you put them in the soil, but they will come back out of the

soil and often move off the field and get into surrounding areas. So, we're doing a bystander exposure and risk assessment.

Another challenge is that there's a lot of variability obviously geographically in terms of the way these chemicals might act in terms of exposure, for example, in California versus Florida and other parts of the country, differences in wind behaviors, temperatures, soil types and so on and so forth. We have most -- the most data we have is more California, and we would probably be relying pretty heavily on that.

Obviously, you don't just compare chemicals directly when you're looking at margins of exposure or however you're looking at this. There are variabilities in the toxic effects that are important to consider as you're characterizing the risks that you're facing and making decisions. Some of these chemicals have near toxic effects, developmental effects. Others are -- affects the eyes in terms of

irritation. Others can affect and expect to see lung damage.

Again, I'm not saying that these effects occur normally, and let me be clear here. These are the end points upon which he with base our regulation, okay? So, the doses would have to be high enough for you to be able to see those effects.

And finally, finding practical risk management that, you know, will actually work, you know, in terms of being able to implement it and being able to enforce it and so on and so forth. People have talked about a number of things. California has talked about permitting processes. In fact, they have some in place, I think. There are differences in application methods, sprinkler, drip. There are different ways of using tarps in terms of timing and the type of materials that the tarps are made of. You can look at differences in field sizes and rates, and I could go on, but obviously it's a pretty complex situation in terms of figuring

out what would be a practical way to mitigate any risks that we find.

In terms of the schedule, I just thought I'd go straight through through the end of this calendar year or next calendar year, I'm sorry, that's when we hope to make a decision on these. Right now, we have started, actually last week, a registrant error only and USDA review of the individual preliminary risk assessment. I hope most of you are familiar with the way we run our public process here. This is a standard part of what we call phase one typically of our public process. That's generally a 30-day period that's allowed for that.

What we're looking for there is strictly actual errors made in the assessment, things like calculation errors, using the wrong formula, not including data that we had and just misplaced, something like that. So, we're looking for errors.

The next slide, during the November and

January -- through January time frame, we will consider the registrant error and USDA comments. So, I should point out that we will also have in that time frame public comments on metam sodium that we will be able to review. The public comment period on the metam sodium risk assessment that was put out August 31st, that public comment period is ending I think in about a week. So, we'll have those comments to look at as well.

We will also during this time be looking at SAP recommendations. That should come out relatively soon, I'm expecting within the month, about some distributional exposure modeling -- models that we took to two SAP meetings in recent months for -- and those are principally to give us better ways of using models to predict the exposure that bystanders will have as the people, again, that are working or living around these treated fields. And during that time frame, then, we will revise these preliminary risk assessments based on

consideration of all of the above.

In February, we are going to have another, possibly shortened, but we will have another registration error only and USDA review of the agency modifications that were based on the SAP recommendations regarding these distributional exposure models. This aspect of the risk assessment is not currently in the documents that people are reviewing right now, and so we're going to afford another opportunity to look at that information before we go public with the documents.

In March, we will have -- that's when the Agency will be considering all of the registration -- again, the registrant error only and USDA review of those modifications that we had made based on the SAP recommendations, and we will revise the risk assessments one more time. And then at that point we will go out with a 60-day public comment period on the preliminary risk assessments.

In the June-July time frame, the Agency

will be considering the public comments we receive on the preliminary risk assessments, and we will also be working toward completion of a preliminary benefits assessment and some risk management options.

And then in the August-September time frame, we will have another 60-day public comment period on those revised risk assessments that would have been revised based on the public comment we received, the preliminary benefits assessments and the preliminary risk management options. During this time period, we also anticipate having a technical briefing. We think that would be valuable for the stakeholders as they develop their public comments because of the complexity and broad stakeholder interest in this, and we thought actually some face-to-face interactions would be helpful rather than just written materials there.

Finally, in the October to December time frame is when the Agency will consider the

public comments on all of that, the revised risk assessments, the benefits assessments, the risk management options, and in consultation with all of the stakeholders, we plan to reach decisions on whether any risk management is needed for these six soil fumigants.

I think that's it.

MR. JONES: Questions? Carol?

CAROLINE: This might be a dumb question, but why are we spending your resources on looking at methyl bromide in this group since it's supposed to be going away?

MS. EDWARDS: Well, it's current -- it's in the queue to complete all of its tolerance reassessments by August of 2006, and I don't think it will be entirely gone by August of 2006, so --

MR. JONES: I think as you know, the U.S. Government has sought critical use exemptions under the provision of the Montreal protocol that allows for that, and I don't think that we see that process, the critical use

exemption process, not being available in the foreseeable future, and so we want to make sure that the product is appropriately regulated while critical use exemptions are -- continue to be in place.

UNIDENTIFIED MALE: I would also like to point out that there are significant quarantine and preshipment uses which are also available and would require in many instances review.

MR. JONES: That's right.

CAROLINE: I told you it might be a dumb question.

MR. JONES: No, it --

MS. EDWARDS: And that's where a lot of the tolerances are, for commodity treatment.

MR. JONES: Jerry?

JERRY: Thank you. Lois, I was just wondering, is there coordination going on within Registration Division at the end of this period that the products that are not registered now can proceed through the registration process, or

is that going to start after that point? I guess the question is, what's the time lines for these unregistered materials and for this --

MS. ROSSI: You are talking about the one active ingredient --

JERRY: Yeah, the methane and dazomet.

MS. ROSSI: Well, what we have basically said is it will stay in the public participation process, but it could be registered at any time along the way in the process, but depending upon the results of the risk assessment.

MR. JONES: I saw another -- Steve.

STEVE: I have a quick question for Debbie. Are any of these reviews going to be truncated, shortened, under the policy of public participation, which you just mention here? You did mention that the time period might be shortened a little bit. Is that just on the error part or --

MS. EDWARDS: That would only be the error part, and I'm not even sure that will

happen. It depends on how much the documents get changed, but we're hoping to keep the error correction part simply to the part that they hadn't seen before, you know --

STEVE: Right.

MS. EDWARDS: -- but I'm not sure yet, but yeah, everything else is pretty typical.

STEVE: Okay, thanks.

MR. JONES: All right, I think -- whoops. Erik? I was about to call you Jennifer for a second there, but --

ERIK: Yeah, I'll be Jennifer.

My question is twofold. One is, there are -- there is some investigation I understand into alternatives to fumigants using tarping alone, without the fumigants, that we've heard about, and I'm wondering if that -- is EPA doing any research on that? Are you -- is USDA supporting that research? We've heard about it in Wisconsin, for example, and I'm just wondering whether that's an active area of research right now.

UNIDENTIFIED MALE: Solarization.

UNIDENTIFIED MALE: Solarization is what they're calling it.

MS. EDWARDS: I'm not aware that we are doing any research. I don't know, are you --

UNIDENTIFIED MALE: Yeah, that's an area that USDA has worked on for a number of years, as also we have had the methyl bromide alternatives program, and results, as I understand it, are varied. Certainly there are disadvantages in that you have to keep the field out of production for a while while you're doing the process, and it doesn't work too well in cold climates, but one of the many things, you know, it's not a cure-all, but it does apparently work in some cases.

ERIK: Is there someone at USDA that we should talk to to find out about those? Would you be the right person?

UNIDENTIFIED MALE: We can certainly -- I can certainly tell you who the right person is, or maybe Dan Botts knows about it. A lot of

it has been done in Florida in the Fort Pierce facility, AR's facility, Fort Pierce.

Dan, do you know?

DAN: The primary ARS researcher who's been working on this, Dan Chalimi at ARS, he started out at the University of Florida, there has been a tremendous amount of work done on solarization as an alternative, and there is a place in certain production systems and cycles for it, but I would remind you that there are very few places in the U.S. that are similar to the Negev Desert, which is where it was developed.

A lot of the areas that have attempted to take advantage of it, especially in Florida, it's a timing issue, and when the fields are fallow, that would be allowed for fumigation -- for solarization, are not the time periods when you have the clear sky, high solar input type situations. It's usually the middle of the summer where you have thunderstorms coming through every three hours, and every time it

clouds up and rains, you lose the impact of the solarization.

The few places where it's worked have been atypical seasonal periods where you have abnormal periods of sunshine, and all that's done for us in most cases has reduced pest level to a more manageable level. It's not an alternative to methyl bromide.

ERIK: Well, we would like to pursue that, because we did here -- I heard a presentation about how it's working in Wisconsin for some of their vegetable crops and fruits -- and potatoes. So, it's something that we're interested in pursuing.

My other question is about methyl bromide and how -- I don't think Caroline's question was stupid at all. The question is really what is the process that you're going to go through in deciding whether or not to apply for those exemptions again, and how does that feed into this process? How are the two linked or related?

UNIDENTIFIED MALE: The Office of Air manages the critical use exemption process for the EPA and then coordinates with a number of other federal agencies, and ultimately decisions are made in a collaborative way that go through the State Department, because it's part of an international process.

What we have been doing in the Pesticides Program has been providing our knowledge and expertise around benefits and use associated with methyl bromide and the alternatives, and that expertise is certain going to be important in our regulatory development, and we're closely working with the air program on timing of our regulatory decision-making, and we're including them in our internal discussions, as they obviously have an interest as well in the process.

ERIK: So, the results of this FQPA review will be fed into that process? That part I didn't really get.

UNIDENTIFIED MALE: Well, you know,

ultimately the choices that we make influence that process, but I think it's too premature in our assessment to be able to predict how it will, but obviously that -- we need to stay in close and coordination with the Air Program and others in the Executive Branch that are working on the critical use exemption, and they're aware of what we're doing, we're aware of what they're doing.

MR. JONES: Okay, I believe we have one public commenter, Paula Bodie with the Scott's Company.

MS. BODIE: Yes, Paula Bodie with the Scott's Company.

My question is really for Lois. I'm sorry I didn't catch you while you were doing your presentation, but this will be quick. First I wanted to thank and congratulate RD's management of registration decisions this year under PRIA, but my question really is on non-PRIA actions. Are you finding that -- have the number of decisions or the timing of the

non-PRIA actions been affected by the workload and deadlines set by PRIA? And do you track the timings, like, or the level of decisions this PRIA year compared to previous years?

MS. ROSSI: By non-PRIA actions, do you mean like the fast-track amendments or --

MS. BODIE: Fast-tracks -- fast-track, new registrations and amendment, yes.

MS. ROSSI: Well, new registrations are covered -- I mean, they are the --

MS. BODIE: I'm sorry, then, the fast-track amendments --

MS. ROSSI: The fast-track amendments, and then -- were you also referring to stuff that was in-house prior to PRIA?

MS. BODIE: Right.

MS. ROSSI: Okay, on the fast-track amendments, I don't think there's a noticeable difference in the numbers and the timing, although I don't think we've really collected -- I don't think we've analyzed this year the time it's taken for the fast-track amendments. I

think we still have some numbers, but I don't think we've analyzed the time.

On the non-PRIA actions that were pending, basically what we've been able to do is try and incorporate those, particularly like, you know, the me-toos that were pending before PRIA was enacted and like, for example, our acute toxicity team basically got rid of their backlog, their backlog being defined as everything that they had in-house before PRIA. So, we've just been concentrating on getting rid of that backlog on those types of actions.

For new uses, we're obviously scheduling the PRIA paid actions or the VOL paid actions, as we call it, we're scheduling those as a priority, and then, depending upon how the resources go, we'll look at the nonpaid, but for the most part, our new uses, in our conversations with companies, those uses that they didn't really pay, they are really not interested in anymore. They have been in-house for a while, and -- so, that's how we're

handling it.

MR. JONES: All right. Well, with that, I want to thank you all for your participation, the dialogue, the advice that you've proffered today. I look forward to another productive half-day session tomorrow. We will start promptly at 9:00 a.m. I look forward to seeing you all then. Thanks.

(Whereupon, the meeting was adjourned.)

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